

May 15, 2007

Action

MEMORANDUM

May 11, 2007

TO: County Council

FROM: Amanda M. Mihill, Legislative Analyst *AMihill*
Michael Faden, Senior Legislative Attorney

SUBJECT: **Action:** Board of Health Regulation restricting trans fat use in eating and drinking establishments

Health and Human Services (HHS) Committee recommendation (2-0, Councilmember Trachtenberg abstaining): Approve the regulation with amendments to delay and split its effective date, and allow restaurant owners to seek waivers for certain food products if a replacement product is not widely commercially available. Councilmember Trachtenberg was concerned that the Committee's recommended amendment may lead to enforcement problems and may become a loophole for restaurant owners, and therefore abstained from voting on the amendment or the regulation as amended.

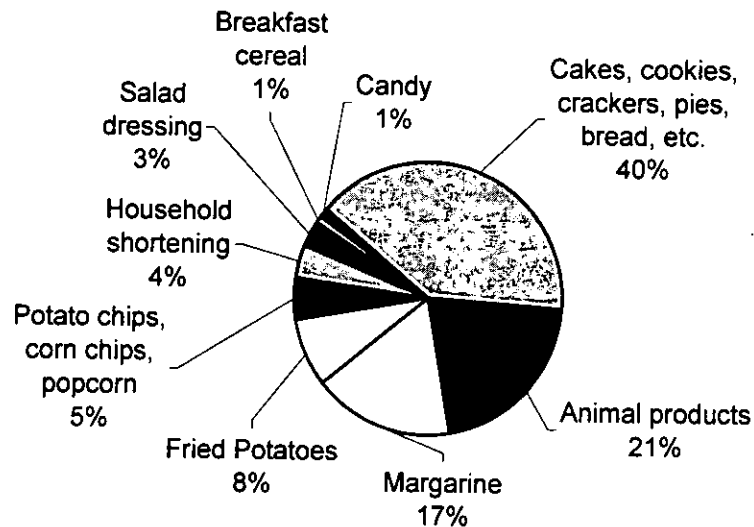
A resolution to adopt a Board of Health Regulation restricting artificial trans fat use in eating and drinking establishments, sponsored by Councilmembers Trachtenberg, Leventhal, Elrich, Ervin, and Knapp, was introduced on March 27, 2007. A public hearing was held on April 24, at which 5 speakers testified. The HHS Committee discussed the Regulation at a worksession held on May 3 and recommends (2-0, Councilmember Trachtenberg abstaining) approval with amendments. Select correspondence and written testimony submitted to the Council is attached on ©9-26.

Background

What is Trans Fat? Trans fat is a specific type of man-made fat formed when liquid oils are converted to solid fats. A small amount of trans fat is found naturally in some animal-based foods. This naturally-occurring trans fat is not subject to the proposed regulation and is not discussed further in this memorandum. Artificial trans fat is created during a process called hydrogenation, when hydrogen is added to liquid vegetable oil to make the oil more solid. Hydrogenation increases the shelf life and flavor stability of foods containing hydrogenated oils.

Chart 1 below identifies the major food sources of trans fat for American adults, according to the U.S. Food and Drug Administration (FDA).

Chart 1: Major Food Sources of Trans Fat for American Adults



What Health Concerns are Associated with Trans Fat? The FDA concluded that consumption of trans fat raises low-density lipoprotein (LDL, or “bad” cholesterol) and increases the risk of coronary heart disease (CHD). The National Institutes of Health (NIH) identified that high LDL cholesterol levels lead to the build up of cholesterol in arteries; the higher the level of LDL in a person’s blood, the greater the risk of CHD. Organizations such as the American Heart Association emphasize that trans fat also lowers high-density lipoprotein (HDL, or “good” cholesterol). HDL carries cholesterol from other parts of the body to the liver, which removes the cholesterol from the body. The higher the level of HDL in a person’s blood, the lower the risk of developing CHD.

CHD occurs when the arteries that supply blood to the heart become hardened and narrowed due to a buildup of material on the inner wall of the artery. When arteries become clogged, blood flow to the heart is reduced, which can result in angina or a heart attack. Over time, CHD can weaken the heart and result in heart failure or arrhythmias. According to NIH, CHD is the most common type of heart disease and the leading cause of death in the United States in both men and women. The Center for Science in the Public Interest (CSPI) cites Harvard researchers as estimating that trans fat causes approximately 50,000 fatal heart attacks each year in the U.S.

Another health concern often associated with trans fat is obesity, although there is no scientific consensus around a strong connection between trans fat and obesity. Obesity is essentially

caused by an imbalance in caloric intake and caloric consumption by the body. However, one recent study concluded that, in equivalent diets, trans fat consumption increases weight gain.¹

What would the Proposed Regulation do? This Board of Health regulation would prohibit an eating and drinking establishment² from storing, distributing, holding for service, using in the preparation of any menu item, or serving food that contains artificial trans fat unless the food is served in the manufacturer's original sealed package. For purposes of the regulation, food contains artificial trans fat if the food:

- (A) is labeled as containing vegetable shortening, margarine, or any kind of partially hydrogenated vegetable oil;
- (B) lists vegetable shortening, margarine, or any kind of partially hydrogenated vegetable oil as an ingredient; or
- (C) contains vegetable shortening, margarine, or any kind of partially hydrogenated vegetable oil.³

The definition excludes food that has less than 0.5 grams of trans fat per serving. The regulation would also require eating and drinking establishments to maintain documentation indicating whether food that is stored, distributed, held for service, used in preparing any menu item, or served contains vegetable shortening, margarine, or any kind of partially hydrogenated vegetable oil, or indicating the food's trans fat content. As drafted, the regulation would take effect on January 1, 2008.

Action in Other Jurisdictions. In December 2006, the New York City Board of Health adopted a health regulation restricting the use of trans fat in restaurants under its jurisdiction. The regulation before the Committee is modeled on the New York City regulation, which takes effect on July 1, 2007 for oils, shortenings, and margarines used for deep-frying and spreads, and July 1, 2008 for oils or shortenings used for deep-frying yeast dough, cake batter, and other foods containing trans fat. In February 2007, Philadelphia adopted a similar regulation, which takes effect on September 1, 2007 for oils, shortenings, and margarines containing artificial trans fat used for frying or in spreads and September 1, 2008 for all other uses of foods with artificial trans fat. Several other jurisdictions have embarked on education campaigns to encourage restaurants to voluntarily eliminate trans fats.

Since the New York City and Philadelphia regulations have not taken effect yet, Council staff has little information regarding potential implementation problems.

Maryland General Assembly Action. During the 2007 General Assembly session, members introduced three bills that would prohibit the use of artificial trans fats on a variety of levels.

¹ www.medicalnewstoday.com, "Trans Fat Leads to Weight Gain Even On Same Total Calories, Animal Study Shows", June 15, 2006.

² The term used for restaurants and other food service facilities in County law (Code §15-1(d),(f)) and regulations. The terms "eating and drinking establishment", "establishment", "food service facility", and "restaurant" are used interchangeably throughout this memorandum.

³ Council staff notes that the regulation should be corrected throughout to read "partially hydrogenated vegetable shortening, margarine, or [any kind of partially hydrogenated] vegetable oil" because there are some shortenings and margarines that do not contain artificial trans fat and should not be subject to the proposed regulation.

The fiscal notes for these bills are attached on ©36-48. Ultimately, none of these bills were enacted. The legislature instead asked the State Department of Health and Mental Hygiene (DHMH) to develop a plan to encourage restaurants to reduce their use of trans fat. This plan is scheduled to be presented to state lawmakers before the 2008 Assembly session.

Issues/Committee Recommendations

1. Voluntary or Regulatory Action?

The Council has received comments from individuals who support the proposed regulation. Some organizations, such as the Grocery Manufacturers/Food Products Association (GMA/FPA), opposed this regulation and suggested that the Council encourage food service facilities to voluntarily eliminate trans fats from their establishments. The threshold question for the Council is should the County *encourage* or *require* restaurants to eliminate the use of trans fat? As part of this discussion, the Council must decide whether a voluntary effort would effectively reduce or eliminate the use of trans fats in County restaurants.

The health concerns associated with trans fat have been in the national spotlight for several years. The FDA first considered proposals to put information about trans fat on nutrition labels in 1991, but did not do so because the scientific evidence about the effects of trans fat at that time was inconclusive. In 1999, the FDA proposed a rule to require nutrition labels to separately identify the amount of trans fat in each food serving. The agency reopened the comment period for this proposal in 2000 and 2002. In 2003, the FDA adopted a final rule requiring nutrition labels to separately identify the amount of trans fat in each food serving. That rule took effect on January 1, 2006. A summary of the final rule is attached on ©31-35.

Although some County restaurants have eliminated or are in the process of eliminating trans fats from their restaurants (e.g., Silver Diner, Black's, Marriott, Taco Bell, Kentucky Fried Chicken, Dunkin' Donuts), many continue to use ingredients with trans fats despite the well-known health concerns.

Before enacting its health regulation, New York City undertook a one-year campaign to educate the City's restaurants about the health dangers of trans fats and requested restaurants discontinue using products containing trans fat. The City Department of Health and Mental Hygiene reported that this effort did not result in a substantial decline in the use of trans fats in City restaurants.

Because a voluntary effort may not significantly reduce the level of trans fat used in County restaurants, more restrictive measures may be necessary to protect public health. **Committee recommendation: adopt the regulation.**

2. Deference to State Action

Organizations such as the Maryland Retailers Association (MRA) and the Restaurant Association of Maryland (RAM) urged the Council to defer action on the proposed regulation until DHMH completes its plan to encourage restaurants to reduce or eliminate trans fats.

The Committee did not support waiting for the General Assembly to act on the use of trans fat in restaurants. The County has taken the lead on other health issues and acted before the State. The most notable example is the County law prohibiting smoking in almost all County restaurants, which the Council enacted in 2003; not until this legislative session did the General Assembly take similar action. The only deadline associated with the state action is that a **plan** must be created by the end of 2007 to educate restaurant owners about the dangers of trans fat. Implementing that plan could take additional months or years.

3. Effective Date

Organizations, such as RAM and Dunkin' Brands, expressed concern about the effective date of the proposed restriction. These organizations articulated several issues that relate to the effective date, including lack of supply, effect on small restaurants, and a potential unwanted increase in the use of saturated fat.

Supply of Artificial Trans Fat Free Products. RAM and GMA/FPA contended that if the regulation takes effect when proposed, there will be an inadequate supply of alternative oils. RAM noted that the annual demand for partially hydrogenated oils is about 8 billion pounds but the current supply of trans fat free oils is only 4 billion pounds. GMA/FPA argued that "planting, harvesting, and processing new crops for fats and oils will take several years to meet the production demand of the entire food industry."

On the other hand, CSPI noted that the consumer demand of trans fat free oils has spurred increased production of these oils. CSPI conceded that the "entire restaurant industry cannot change oils overnight", but argued that "parts of the industry and parts of the country can easily change". CSPI estimates that County restaurants only use about one-sixth of one (0.17) percent of the nation's shortenings and oils. Similarly, Whole Harvest Products and Stephen Joseph of BanTransFat.com asserted that there is not a lack of supply of trans fat free oils.

Council staff is persuaded that there is currently an adequate supply of trans fat-free oils to supply the County's food service facilities with the required level of trans fat-free oils. As demand for trans fat free oils increases, the market will respond and the supply of those oils is likely to increase as well.

Small Restaurants. RAM argued that small restaurants, including some ethnic restaurants, may face an economic disadvantage if the regulation is adopted as proposed. RAM contended that, although national chain stores will likely have the buying power to enter into long-term contracts for trans fat free oils and will likely be able to absorb any increased cost, smaller restaurants may not be able to do the same. RAM estimated that trans fat-free oils cost 15-20 percent more than oils with trans fats. RAM argued that this increased cost for smaller restaurants will result in either increased costs for consumers or a smaller profit margin.

Questioned at the public hearing, Michael Jacobsen of CSPI estimated that oils and shortenings account for only 1-2 percent of a restaurant's costs. Council staff expects that, as the demand for trans fat-free products increases, the supply of those products will increase, which in turn is

likely to drive the cost of those products down. If the Committee opts to delay the effective date of the regulation, this would give small businesses more time to find appropriate suppliers.

Use of Products with Higher Saturated Fat. Both RAM and GMA/FPA argued that if the Council adopts the proposed regulation, restaurant owners will replace oils containing trans fats with oils high in saturated fats, which has its own serious health concerns. Food suppliers may not automatically replace oils containing trans fat with oils high in saturated fat. However, even if they tend to do so, the result would be some improvement in public health. The Harvard School of Public Health concluded that trans fat is worse for cholesterol levels than saturated fat.⁴ Therefore, although saturated fats may not be healthy, gram for gram, they are better than trans fats.

Recipes that Contain Products with Artificial Trans Fat. Organizations such as Dunkin' Brands and RAM contended that replacing trans fats in baked goods will be particularly challenging and requested that the Council allow more time for restaurants to reformulate recipes to comply with the regulation. The Council received additional correspondence from County resident Dennis Walsh suggesting that the Council limit the regulation to restrict the use of oils with trans fat in frying, but not restrict the use of trans fat in foods such as baked goods.

If the Committee is inclined to accept the prevailing evidence on the health dangers associated with trans fat, Council staff does not recommend limiting the regulation to food cooked in fryers. As the Chart on page 2 shows, baked goods such as cakes, pies, and cookies account for about 40 percent of the average American adult's intake of trans fats. Alternatives exist to replace the ingredients in these baked goods that contain trans fats with ingredients that are trans fat-free.

Regarding the effective date, Council staff notes that chain establishments may not need an additional year to reformulate recipes because the New York City regulation takes effect on July 1, 2008 for food containing trans fat. Therefore, theoretically, for these restaurants, a 6-month delay until July 1, 2008 may be adequate. However, because the County has stand-alone restaurants as well as chain restaurants that may not operate in New York City, Council staff believes that postponing the effective date of the regulation, especially for recipes that may require reformulation, may be appropriate to cushion its effect on smaller restaurants.

Compliance Issues. RAM suggests the Council set an effective date later than the effective dates of the New York City and Philadelphia regulations to allow adequate time to address any compliance issues that may arise in implementing those regulations. RAM proposed an effective date of July 2009, which would be one year after the second phase of New York City's regulation. Council staff does not recommend that the Council defer action on this regulation until the New York City and Philadelphia regulations take effect. If the Council approves amendments discussed below, the Council could still modify to the adopted regulation if unforeseen compliance issues arise.

⁴ www.hsph.harvard.edu/nutritionsource/fats.html.

Options Discussed by the Committee. At its May 3 worksession, the Committee discussed the following options to address these concerns:

Delay the Effective Date

Councilmember Berliner offered an amendment to delay and split its effective date, and allow restaurant owners to seek waivers for certain food products if a replacement product is not widely commercially available. The following language is included in the attached regulation:

- (g) **Effective Date.** This regulation takes effect on:
 - (1) January 1, 2008 for oils, shortenings, and margarines with artificial trans fat that are used for frying or in spreads; and
 - (2) January 1, 2009 for:
 - (A) oils or shortenings used for deep frying of yeast dough or cake batter; and
 - (B) all other foods containing artificial trans fat.
- (h) The Director of Health and Human Services may delay the applicability of this regulation to any food covered by subsection (g)(2)(B), after receiving a request from an eating and drinking establishment, for up to one year if the Director finds that the eating and drinking establishment has demonstrated that a suitable replacement product is not widely commercially available. The Director must notify the Council of any decision made on a request under this subsection.

The timeframe in Section (g) would be consistent with the timelines in the New York City and Philadelphia regulations, which take effect for frying oils 10 months and 9 months after introduction of the regulation, and 22 and 21 months for other foods containing artificial trans fat.⁵ Councilmember Trachtenberg was concerned that the Committee's recommended amendment may lead to enforcement problems and may become a loophole for restaurant owners, and therefore abstained from voting on the amendment.

Committee recommendation (2-0, Councilmember Trachtenberg abstaining): delay the regulation effective date, which would allow more time for restaurants to reformulate recipes; and allow restaurant owners to seek waivers for a food product if a replacement product is not widely commercially available.

DHHS Response. DHHS has not taken a position on the proposed regulation, but expressed concerns about subsection (h) above (see DHHS memo, ©38). DHHS believes that "the Department does not have the expertise, capacity, or core mission to engage" the food industry to "make the required determinations competently or equitably at this time." In lieu of this case-by-case waiver provision, DHHS recommends that the Council require DHHS to report 3 months before the second phase of implementation on whether that phase should be postponed generally. DHHS noted that additional resources would be required to hire a consultant to generate the report.

⁵ The New York City regulation was introduced in September 2006, adopted in December 2006, and the first phase of implementation takes effect on July 1, 2007. The Philadelphia regulation was introduced in December 2006, adopted in February 2007, and the first phase of implementation takes effect on September 1, 2007.

This amendment would place the burden of persuasion on the restaurant requesting the waiver. Although DHHS will have to do proper due diligence to make an informed decision, the restaurant must demonstrate to DHHS's satisfaction that a food is not widely commercially available. Although Council staff believes a general report may be useful, it would not address the Committee's concern about restaurants being unable to obtain specific trans fat-free products (i.e., a general report may conclude that there is an abundant supply of trans fat free products in the marketplace, but a particular restaurant may still be unable to obtain a trademark product). **Council staff does not recommend modifying the Committee's amendment to require DHHS to report generally on the availability of trans fat-free products in lieu of a case-by-case assessment.**

The amendment as recommended by the Committee would require DHHS to notify the Council of any decision made on a request. DHHS contends that a large number of restaurants could seek waivers, and argues that notifying the Council each time DHHS grants or denies a waiver request could be time consuming. As an alternative to case-by-case reporting, DHHS suggests that the Council require a summary report at the end of the waiver request period. **Council staff recommends this as a viable alternative.**

Grace Period

The Committee discussed, but did not recommend, allowing a grace period after the regulation takes effect where the County would issue warnings instead of fines to restaurants out of compliance with the regulation. This would give County restaurants more time to find suppliers and reformulate recipes without the pressure of potential penalties. New York City took a similar approach and instituted a 3-month grace period after the effective date for each phase when no fines will be assessed if a restaurant is out of compliance with the regulation.

Reference Materials

The Committee also discussed asking DHHS to develop reference materials to give County restaurants additional help during the transition. Those materials could include educational materials regarding the health concerns associated with trans fat, and ways to replace trans fat in baking and frying. New York City took a similar approach and has launched an entire "Trans Fat Help Center" to give City restaurants more information. Although Council staff does not suggest launching a similar center, more information may benefit County restaurants. The County Fiscal Impact Statement (©5-6) envisions that if the Council adopts this regulation, a "Trans Fat Program" will be developed to include education and training materials for County restaurants.

4. Fiscal Impact Statement (©5-6)

The Committee discussed at length the potential fiscal impacts associated with the proposed regulation, as identified by the Office of Management and Budget and DHHS. DHHS estimated that this regulation would require creating 2 full-time Environmental Health Specialists. During the first phase of implementation, DHHS will use these positions to educate restaurant owners about the regulation's requirements. When questioned by Committee members, DHHS indicated that this calculation is based on an assumption that inspectors will need an added 15 minutes per restaurant to review product labels. While it may take more time to review product labels during

the second phase of implementation, Council staff questions the amount of time required to inspect the limited group of labels during the first phase of implementation (when only frying oils are prohibited from containing trans fats). DHHS argued that the resources identified in the fiscal impact statement are in line with the resources that are being sought by the New York City Department of Health and Mental Hygiene to implement its trans fat regulation. At the time this packet went to print, Council staff had been unable to speak directly to New York City representatives to assess the fiscal impacts of the New York City regulation.

5. Enforcement

As drafted, the regulation would assign DHHS the responsibility to enforce this regulation by requiring the Department to investigate each complaint that alleges a violation of the regulation and monitor compliance with the regulation when the Department inspects each food service facility. The regulation would require restaurants to have adequate documentation to indicate the trans fat content of a food or whether the food has shortening, margarine, or partially-hydrogenated vegetable oil. DHHS will ultimately be able to verify compliance by examining the documentation or labels retained by the restaurant. **The Committee did not recommend any change to the enforcement mechanisms.**

The regulation would set the following sanctions for violations: a Class C civil violation (\$50 for an initial violation and \$75 for a repeat violation); the County Attorney or an affected party can sue to enjoin repeated violations of the regulation; and the Director of DHHS can suspend a license for up to 3 days if the owner knowingly and repeatedly violates the regulation.

RAM argued that the proposed penalties are unnecessarily punitive, especially DHHS's authority to suspend an establishment's license. RAM contends that establishments sometimes accept a substitute food product from a supplier when the product ordered is not in stock.

Although Council staff understands this concern, we emphasize that the suspension authority is discretionary (i.e., the language does not require DHHS to suspend an establishment's license, but only gives the Department that authority). Similar authority in current County food health and safety laws is rarely if ever used. Therefore, Council staff does not recommend further modifications. However, if the Committee decides otherwise, one option would be to amend the regulation to authorize DHHS to waive the requirements under extraordinary circumstances. Council staff also notes that, as the demand for trans fat free products increases, the supply should also increase, which would make it less likely that a restaurant would be forced to accept a product that contains trans fat.

6. Applicability to Grocery Stores

MRA and Giant Food requested that grocery stores and supermarkets be exempt from this regulation. RAM does not support exempting these retailers.

As drafted, the regulation would apply to products sold in stores such as supermarkets. The regulation would not restrict a grocery store from selling products that contain artificial trans fat if the product is sold in the manufacturer's original package (e.g., a box of crackers or cookies),

but the regulation would prohibit the store from selling food that contains artificial trans fat and is not sold in the manufacturer's original package (e.g., food prepared in a supermarket deli or bakery). **The Committee recommended that food produced in supermarket departments, such as a bakery or deli, should be subject to the same restriction as food products in restaurants.** The public health concerns associated with trans fats is the same regardless if the food is prepared in a restaurant or a supermarket deli.

7. Miscellaneous Issues

Definition of Eating and Drinking Establishment. RAM requested that the proposed regulation clearly define what constitutes an eating and drinking establishment, and suggests that the resolution be amended to include the definition of eating and drinking establishment in County Code §15-1. Council staff notes that the regulation provides that "any term used in this regulation has the same meaning as in Section 15-1 of the County Code if the term is defined in that Section." Section 15-1 defines an eating and drinking establishment as "any food service facility" and defines a "food service facility" as:

Any enterprise that prepares or sells food or drink for human consumption on or off the premises. Food service facility includes:

- (1) Any restaurant, coffee shop, retail market, cafeteria, short-order cafe, luncheonette, tavern, sandwich stand, soda fountain; and
- (2) Any food service facility in an industry, institution, hospital, club, school, church, catering kitchen, or camp.

Because an eating and drinking establishments is defined in §15-1, **the Committee did not recommend defining the term again.**

Foods Prepared On-Site. RAM contends the proposed regulation is intended to regulate the trans fat content of food that is prepared on-site, but the regulation as drafted would restrict only food that is served directly to customers in the manufacturer's original packaging. Council staff does not believe the regulation was intended to exempt food items that were prepared off-site unless the food is sold in the manufacturer's original packaging. The public health concerns associated with the use of trans fats in food is the same whether the food is prepared on-site or off-site (e.g., if a restaurant makes a pie in the restaurant or purchases a pie from a food supplier). **The Committee did not recommend amending the regulation to exclude permanently food prepared off-site from the requirements of the regulation.**

Corporate Changes. RAM noted in their written testimony that many chain restaurants may not have any flexibility in the products that they use, and local compliance with the County's regulation would require corporate changes since many food products are supplied through corporate headquarters. Council staff notes that several restaurant chains are already switching their products to those that are trans fat-free, and many other chains will make those changes to comply with the New York City and Philadelphia regulations. Although not every restaurant in Montgomery County necessarily has a sibling in New York City or Philadelphia, compliance with those regulations is likely to show that corporate changes can be made when required. **The Committee did not recommend any special exemption for chain restaurants.**

Substitute Products. RAM contends that consideration must given to restaurants for products that are purchased ready-to-cook (e.g., french fries and chicken nuggets). RAM notes that acquiring these types of products would require cooperation from the manufacturer and/or food service supplier and may take time to modify these products, unless the restaurant designs its menu around the supplier's product availability. **If the Council approves the Committee's recommended amendment to delay the regulation's effective date, restaurants would have more time to find suitable replacements.**

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Resolution No.: 16-
Introduced: March 27, 2007
Adopted: _____

COUNTY COUNCIL
FOR MONTGOMERY COUNTY, MARYLAND
SITTING AS THE MONTGOMERY COUNTY BOARD OF HEALTH

By: Councilmembers Trachtenberg, Leventhal, Elrich, Ervin, and Knapp

Subject: **Board of Health Regulation restricting trans fat use in eating and drinking establishments**

Background

1. County Code §2-65, as amended effective August 10, 2000, provides that the County Council is, and may act as, the County Board of Health, and in that capacity may adopt any regulation which a local Board of Health is authorized to adopt under state law.
2. Maryland Code Health-General Article §3-202(d) authorizes the County Board of Health to adopt rules and regulations regarding any nuisance or cause of disease in the County.
3. On April 24, 2007, the County Council held a public hearing on this regulation. As required by law, each municipality in the County and the public were properly notified of this hearing.
4. The County Council, sitting as the Board of Health, finds after hearing the testimony and other evidence in the record of the public hearing that restricting trans fat use is necessary to protect the health of patrons of eating and drinking establishments in the County.

Action

The County Council for Montgomery County, Maryland, sitting as the County Board of Health, approves the following regulation:

Artificial trans fats in eating and drinking establishments

(a) **Definitions.**

- (1) Any term used in this regulation has the same meaning as in Section 15-1 of the County Code if the term is defined in that Section.
- (2) ***“Artificial trans fat”*** means the specific type of fat formed when hydrogen is added to liquid vegetable oil to make the oil more solid. This process is called hydrogenation. For purposes of this regulation, a food contains artificial trans fat if the food:
 - (A) is labeled as containing partially hydrogenated vegetable shortening, margarine, or [any kind of partially hydrogenated] vegetable oil;
 - (B) lists partially hydrogenated vegetable shortening, margarine, or [any kind of partially hydrogenated] vegetable oil as an ingredient; or
 - (C) contains partially hydrogenated vegetable shortening, margarine, or [any kind of partially hydrogenated] vegetable oil.

However, a food with a nutrition facts label or other document from the manufacturer that lists the trans fat content of the food as less than 0.5 grams per serving does not contain artificial trans fat.

- (b) **Artificial trans fats restricted.** Any food containing artificial trans fat must not be stored, distributed, held for service, used in preparing any menu item, or served in any eating and drinking establishment. This subsection does not apply to any food that is served directly to patrons in the manufacturer’s original sealed package.

(c) **Labels.**

- (1) **Original label required.** Except as provided in subsection (2) and (3), each eating and drinking establishment must maintain on site the original label for any food that:
 - (A) contains fat, oil, or shortening;
 - (B) is required by federal or state law to have a label when bought by an eating or drinking establishment; and

(C) is stored, distributed, held for service, used in preparing any menu item, or served by the eating and drinking establishment.

(2) **Documentation instead of labels.** An eating and drinking establishment may provide documentation acceptable to the Department of Health and Human Services from the manufacturer of a food, indicating whether the food contains partially hydrogenated vegetable shortening, margarine, or [any kind of partially hydrogenated] vegetable oil, or indicating the food's trans fat content.

(3) **Documentation required when food products are not labeled.** If any food that is restricted under subsection (b) contains fat, oil, or shortening and a label was not required when the food was bought, an eating and drinking establishment must maintain documentation acceptable to the Department of Health and Human Services from the manufacturer of the food indicating whether the food contains partially hydrogenated vegetable shortening, margarine, or [any kind of partially hydrogenated] vegetable oil, or indicating the food's trans fat content.

(d) **Enforcement.**

- (1) Any violation of this regulation is a Class C civil violation. Each day a violation exists is a separate offense.
- (2) The County Attorney or any affected party may file an action in a court with jurisdiction to enjoin repeated violations of this regulation.
- (3) The Department of Health and Human Services must investigate each complaint alleging a violation of this regulation and take appropriate action, including issuing a civil citation when compliance cannot be obtained otherwise.
- (4) When an eating and drinking establishment is inspected by the Department of Health and Human Services for compliance with Chapter 15, the Department must verify compliance with this regulation.
- (5) The Director of Health and Human Services may suspend a license issued under Chapter 15 for up to three days if the Director finds, under the procedures of Section 15-16, that the operator of an eating and drinking establishment has knowingly and repeatedly violated this regulation.

(e) **Applicability.** This regulation applies Countywide.

- (f) **Severability.** If the application of this regulation or any part of it to any facts or circumstances is held invalid, the rest of the regulation and its application to all other facts and circumstances is intended to remain in effect.
- (g) **Effective Date.** This regulation takes effect on:
- (1) January 1, 2008 for oils, shortenings, and margarines with artificial trans fat that are used for frying or in spreads; and
 - (2) January 1, 2009 for:
 - (A) oils or shortenings used for deep frying of yeast dough or cake batter; and
 - (B) all other foods containing artificial trans fat.
- (h) The Director of Health and Human Services may delay the applicability of this regulation to any food covered by subsection (g)(2)(B), after receiving a request from an eating and drinking establishment, for up to one year if the Director finds that the eating and drinking establishment has demonstrated that a suitable replacement product is not widely commercially available. The Director must notify the Council of any decision made on a request under this subsection.

This is a correct copy of Council action.

Linda M. Lauer, Clerk of the Council



OFFICE OF MANAGEMENT AND BUDGET

Isiah Leggett
County Executive

Joseph F. Beach
Acting Director

MEMORANDUM

TO: Marilyn J. Praisner, Council President
Montgomery County Council

FROM: Joseph F. Beach, Director *JFB*
Office of Management and Budget *Beach*

SUBJECT: Board of Health Regulation, Restricting Trans Fat Use In Eating and Drinking Establishments

RECEIVED
MONTGOMERY COUNTY
COUNCIL
2007 MAY - 1 PM 2:38

The purpose of this memorandum is to transmit a fiscal impact statement to the Council on the subject regulation.

REGULATION SUMMARY

The Board of Health regulation would prohibit an eating and drinking establishment from storing, distributing, holding for service, using in the preparation of any menu item, or serving food that contains artificial trans fat unless the food is served in the manufacturer's original sealed package. For purposes of the regulation, a food has artificial trans fat if the food has 0.5 grams or more of trans fat per serving. The Board of Health regulation would also require eating and drinking establishments to maintain documentation indicating whether food that is stored, distributed, held for service, used in preparing any menu item, or served contains vegetable shortening, margarine, or any kind of partially hydrogenated vegetable oil, or indicate the foods' trans fat content.

FISCAL SUMMARY

This regulation would require the permanent creation of two full-time Environmental Health Specialists to develop a Trans Fat Program, including education, regulatory, and enforcement components. Additional first year costs are estimated at \$214,910, including one-time costs for vehicles, cellular phones, and laptop computers. On-going costs are estimated at \$199,690. While it is anticipated an additional position would be required during the start-up year of the program, the impact on other programs can be managed without additional costs.

The Trans Fat Program will consist of the development of regulatory standards and interpretations for compliance, creation of a menu review process, and inspection forms, development and implementation of a training program for the Environmental Health Specialists, and educational and training materials for operators of food service facilities in Montgomery County. The two additional positions will lead the development of the program in the first year and then provide the additional resources necessary to conduct inspections at 2,467 food service facilities to ensure compliance with the regulation.

5

Office of the Director

The following contributed to and concurred with this analysis: Reginald Booker, Senior Administrator Licensure and Regulatory Services, DHHS, Richard Helfrich, Deputy Health Officer, DHHS, Bonnie Leiter, Manager, Budget Team DHHS.

IL:brg

cc: Brady Goldsmith, OMB
Uma Ahluwalia, Director, DHHS
Corinne Stevens, Chief Operating Officer, DHHS
Dr. Ulder Tillman, Health Officer, DHHS

COUNTY MARYLAND



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Councilmember Duchy Trachtenberg to Propose Elimination of Artificial Trans Fats

- Release ID: 07-026
- Release Date: 3/19/2007
- Contact: William Klein 240-777-7830
- From: Office of Duchy Trachtenberg

Councilmember Duchy Trachtenberg to Propose Elimination of Artificial Trans Fats

'Change the Oil' Breakfast on Monday, March 26, Will Introduce Measure to Make Montgomery First County in U.S. to Pass Ban

ROCKVILLE, Md., March 16, 2007—Montgomery County Councilmember Duchy Trachtenberg (D-At-Large), herself a public health professional, will introduce her first major legislation before the County Council on Tuesday, March 27—a regulation restricting use of artificial trans fats for cooking in County restaurants. Passage of her bill would make Montgomery the first County in the nation to ban trans fats in restaurants.

On Monday, March 26, at 10:30 a.m. in the County Executive Office Building cafeteria in Rockville, Trachtenberg will be joined by local and national restaurateurs who are eliminating trans fat from their kitchens. Trans-fat free food will be served to County employees. Nutritional experts will be among those present to explain the importance of replacing the cooking substance with much healthier alternatives.

Trans fat increases LDL ("bad") cholesterol and lowers HDL ("good") cholesterol. While many consumers are taking steps to eat and shop healthier, restaurants remain a significant source of this major link to obesity and heart disease.

Trachtenberg's bill would require that elimination of trans fats in Montgomery County restaurants be in force by Jan. 1, 2008.

Her proposal mirrors similar legislation adopted by the New York City Board of Health in December 2006. According to researchers at the Center for the Science in the Public Interest (CSPI), who will be represented at the March 26 event, Montgomery County would be the first county in the U.S. to take this step.

Trachtenberg, who holds a Masters Degree in Social Work, is a past Governing Councilor and Chair of the Alternative Medicine Section within the American Public Health Association (APHA). She said that the support of major restaurant operators who have already demonstrated their belief in finding alternatives to trans fat oils for their businesses shows that Montgomery County is ready to ban the oils in all restaurants.

"This is a solid example of when government protects public health and at the same time, catches up to public demand," Trachtenberg said. "Following the best practices of food leaders like Marriott, Ruby Tuesday and our own Silver Diner is the right thing to do—and tasty too!"

Marriott International announced this year that it was eliminating trans fats in fried foods and deep frying oils as part of an eight-year effort to remove trans fats from the vast majority of food served at

more than 2,300 Marriott International hotels throughout the U.S. and Canada. Chief Executive Officer Bill Marriott even discussed it on his blog.

"Boy, I just love French fries," he wrote. "I started cooking French fries back in 1950 when I worked in the Hot Shoppes in Salt Lake City. And all my boys joined the company when they were 15 and 16 and worked first cooking French fries in the Hot Shoppes. So I love French fries.

"Unfortunately, we've all learned that the oil with which we cook French fries is a source of trans-fat, and today, that's not good. We know it's been linked to obesity and heart disease. Our team at Marriott has been working on taking these trans-fats out for a long time—for more than eight years."

For more information on the bill that Councilmember Trachtenberg will introduce, contact William Klein at 240-777-7830 or 301-412-1768 (cell).

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Food industry trade groups must come clean on trans fats

By Stephen Joseph

April 16, 2007

Stephen Joseph is the CEO of BanTransFats.com and the CEO of FryTest.com. In May 2003, he filed a lawsuit against Kraft regarding trans fat in Oreo cookies. As a result, Kraft agreed to remove trans fat from its cookies and has now reduced or eliminated trans fat from its products across the board. He also filed a suit against McDonald's for reneging on its promise to reduce the amount of trans fat in its cooking oil, resulting in a \$7.0 million payment to the American Heart Association. He turned Tiburon, California into "America's First Trans Fat-Free City" and worked with New York City on its trans fat initiative. FryTest.com has held a zero trans fat cooking oil contest.

The information campaign

In 2003, I launched BanTransFats.com to campaign against trans fat-laden partially hydrogenated oils. I have spent the last four years waging war against trans fat. While the campaign is not over, it is definitely a success. Everyone in the food industry now accepts that partially hydrogenated oils are on the way out.

I am doing my level best to provide accurate and useful information to government officials, politicians, and the food industry to help the transition to a zero trans food supply. Unfortunately, my efforts have not been mirrored by food industry trade associations.

Exploiting the fact that politicians, many government officials, and the public know virtually nothing about frying oils and baking shortenings, these trade associations have been stirring up baseless fears about supply, fry life, cost, taste, and saturated fat. They also press the emotive 'freedom of choice' button, which is sure to get the politicians all 'charged up,' especially in the United States.

In one respect, these trade associations have been successful. The media parrots their conclusory statements that trans fat-free oils are in short supply, have shorter fry lives, cost more, and taste worse than partially hydrogenated oils (they produce 'soggy fries'). These canards are now part of the conventional wisdom of the media.

Thankfully, these trade associations have scored only a hollow victory. New York City and Philadelphia ignored their non-credible arguments and passed trans fat bans, and many other states and cities are working on bans too. Meanwhile, food manufacturers and restaurants are removing partially hydrogenated oils.

In 2006, I created FryTest.com, a comprehensive information resource about zero trans cooking oils. FryTest.com commissioned Texas A&M University to conduct a zero trans fat cooking oil contest, to compare nine zero trans oils and a leading brand of partially

hydrogenated soybean oil. Partial results of the contest are now available on the FryTest.com website and full results including consumer evaluations will be published soon.

Supply

One trade association has stated: "Useful alternatives are not readily available for the switch to trans-fat free oils." Another asserts that "there is currently not an available supply of oil alternatives."

There is no supply problem. There is a list of available zero trans oils on the FryTest.com website. Many of the manufacturers are huge multinational companies. No restaurant or food manufacturer has ever had or will ever have any trouble obtaining zero trans oil or shortenings. Many oil company executives are deeply frustrated with food industry trade associations making baseless assertions about the supply of their oils, and wish they would stop.

As the CEO of FryTest.com, I am in contact with most of the leading cooking oil manufacturers on a regular basis. They tell me that if there is more than enough zero trans oil to meet existing demand and there will always be a sufficient supply as demand increases.

One major food industry trade association claims that there will be insufficient supply of zero trans oils in 2008 and beyond, citing 2006 and 2007 low lin soybean and high oleic canola acreage figures. (Those oils are only part of the solution.) The acreages for 2006 and 2007 are based on planting decisions made in early 2006 and early 2007. How can a trade association know what will be grown in 2008 and beyond when no planting decisions have been made for those years? It depends on projected demand include any regulations banning partially hydrogenated oils. Farmers will grow the necessary crops if they are paid to do so.

If any oil company is saying that there will not be a sufficient supply of zero trans oils, we should determine whether it is a major supplier of partially hydrogenated oils which stands to lose market share if trans fat bans are enacted.

Fry Life

In the FryTest.com oil contest, Texas A&M University measured the fry life of ten different oils after 300 fryings per oil, including a partially soybean hydrogenated oil. They found that none of the oils came even close to the end of fry life. Some of the zero trans oils actually had better fry lives than the partially hydrogenated oil. The results are on the FryTest.com website for all to see.

Cost

In my frequent conversations with reporters, they invariably tell me that they understand that zero trans oils “cost more”. Each time I ask the reporters how much more? In every instance, they have admitted that they have no clue and have never even asked the question.

I have conducted an informal estimation of how many servings of McDonald’s medium sized French fries (weighing 4oz) can be cooked with one 35lb case of heavy duty zero trans oil. My rough estimate is 3,000 to 4,000 servings. Let’s say for the sake of argument that the case costs \$23 if it’s partially hydrogenated oil and \$28 if it’s zero trans oil. The \$5 price difference per case will be spread over 3,000 to 4,000 servings. Any restaurant that cannot afford that miniscule price difference should not be in business. KFC’s third-largest franchise owner, John Neal, says the difference in cost is “pennies.” When I mention this to journalists, they are usually astounded and feel that they have been misinformed about price.

Taste

49 to 50 consumers evaluated each of the ten oils in the FryTest.com zero trans fat cooking oil contest. The results have not yet been announced, but we should not be surprised if the zero trans oils were preferred by consumers. Partially hydrogenated oils taste dreadful when compared to zero trans oils and that is confirmed by consumer taste tests. The fact is that zero trans oils produce wonderful tasting crispy non-soggy fried food.

Saturated fat

There is one line of attack that the trade associations use as a “throwaway” argument. They say that if trans fat is eliminated, food will be less healthy because saturated fat content will increase.

In fact, if partially hydrogenated soybean oil is replaced with trans fat free soybean oil, the saturated fat level stays the same at about 13-15%. Soybeans are soybeans. And if trans fat free canola oil or high oleic canola replaces partially hydrogenated soybean oil, the saturated fat level is actually halved to about 6-7%. The only exception is palm oil which is more healthy than partially hydrogenated oil because it does not reduce HDL cholesterol. Trans fat is worse than saturated fat. Period.

Freedom of choice

Regarding freedom of choice, I doubt that any consumer anywhere has ever asked for “a portion of trans fat please.” It’s not a choice that people make or can make. Partially hydrogenated oil is an ingredient, not a menu choice. Consumers can still order French fries, fried chicken, donuts, or whatever.

These trade associations want freedom of choice for businesses, not consumers. But surely consumers should have freedom of choice about what they are eating. They have no real freedom of choice in restaurants, because restaurants are not required to disclose that they are using partially hydrogenated oil.

Education

The trade associations say that we should use education, not law. Why should we risk human lives by relying on an education campaign that will only reach a small percentage of the population? And who will pay the huge cost of such an education program? It is easier, cheaper, faster, and more effective to simply change the oils.

Any food industry trade association trying in good faith to serve the best interests of its members should be providing useful information about alternatives to partially hydrogenated oils. After all, they are promoting "education." Unfortunately, that is not what we are seeing.

I am only aware of one state food industry trade association trying to inform its members about alternatives. Major trans fat conferences have been held by health organizations, not food industry trade associations. The American Heart Association held an excellent trans fat conference in 2006, bringing together all affected segments of the food industry.

Conclusion

I hope that food industry trade associations will finally recognize that partially hydrogenated oils are vanishing and that it is time to "get with the program." I believe that they will find that most food manufacturers and restaurant owners disagree with their retrograde approach on this issue.

If food industry trade associations actually took the time to thoroughly research zero trans fat alternatives, they would be forced to admit that the issues that they are raising are non-issues. This applies equally to cooking oils and baking shortenings.

Food industry trade associations have a moral responsibility not to perpetuate the existence of a very harmful food ingredient. They should be taking the lead on public health, not dragging their heels.

**Testimony of Michael F. Jacobson, Executive Director
Center for Science in the Public Interest
Hearing on Artificial Trans Fat
Montgomery County Council
April 24, 2007**

Good Afternoon. My name is Michael Jacobson and I am the Executive Director of the Center for Science in the Public Interest. CSPI is a nonprofit health advocacy organization based in Washington. Among other things, CSPI led the effort to win passage of the law requiring nutrition labeling on packaged foods.

I applaud Councilmember Trachtenberg for introducing a regulation that would largely eliminate artificial trans fat from County restaurants. This important regulation would help protect diners from a very significant cause of heart disease. Harvard School of Public Health researchers estimate that trans fat has been causing about 50,000 fatal heart attacks across the nation each year. Some of those deaths could be prevented by the measure being considered today.

CSPI, in 1993, first called on the U.S. Food and Drug Administration to require the trans-fat content to be listed on food labels. The FDA's labeling regulation went into effect in 2003, and that stimulated many manufacturers to begin using healthier oils. However, restaurants have been slower to act. Still, some major chains, and some smaller restaurants, have greatly reduced the amount of trans fat in their products. Those include Marriott, Silver Diner, and Black's right here in Montgomery County. However, most restaurants have not changed their oils.

The restaurant trade association advocates voluntary programs instead of regulations. Unfortunately, a voluntary program probably wouldn't work well. New York City tried that approach for a whole year, but concluded that few restaurants switched to healthier cooking oils.

The restaurant association contends that there isn't enough trans fat-free oil for the county's restaurants. But, in fact, the marketplace is working. The "pull" of consumer demand has spurred companies to spur oil processors to spur seed developers to spur farmers to grow more crops whose oils could replace

partially hydrogenated soybean oil. We've seen skyrocketing acreages of low-linolenic soybean oil, high-oleic canola oil, and sunflower oil.

While the whole restaurant industry could not change oils overnight, parts of the industry and parts of the country can easily change. If New York and Philadelphia restaurants are changing oils within 18 months, and the entire Wendy's and KFC chains could switch oils, certainly so could restaurants in Montgomery County. After all, county restaurants use only one-sixth of one percent of the nation's shortenings and oils. Supplies of those ingredients will be entirely sufficient to meet the restaurants' needs.

In conclusion, I urge the Council to fulfill its responsibility to protect the public's health by promptly getting artificial trans fat out of county restaurants.

Thank you.

March 29, 2007

2007 APR -2 AM 9: 54

The Honorable Councilmember Duchy Trachtenberg
Montgomery County Council
100 Maryland Avenue
Rockville, Maryland 20850

027464

Re: Proposed Trans Fat Ban

Dear Councilmember Trachtenberg

I am writing concerning your proposal to ban trans fats from restaurants in Montgomery County. In behalf of Dunkin' Donuts, I ask that in crafting its resolution, the city provide the same consideration as did the New York City Board of Health when it determined to extend the deadline for banning trans fats in frying oils used for producing donuts to July 1, 2008, instead of July 1, 2007.

For convenience, the New York provision is enclosed; the special exception for donuts is contained in section 81.08(d).

The New York City Board of Health determined to allot additional time for the creation of trans fat-free donuts after receiving a presentation from our head of Research and Development regarding the state-of-the-art in the effort to produce fresh donuts that are trans fat-free. I would like to share that information with you.

At Dunkin', we wholeheartedly embrace the objective of making trans fats a thing of the past. In fact, Dunkin' Donuts acted independently in 2004 and declared a goal of removing trans fats from all of our products. We are well on our way to achieving that goal. We have completely removed artificial trans fats from all of our permanent product lines other than donuts.

We are working hard to remove the trans fats from donuts at our research and development facility, which employs twenty-one chefs and food scientists in a 25,000 square-foot laboratory. The production of trans fat-free bakery products like donuts poses a much greater challenge than does, say, trans fat-free French fries or chicken. It has to do with the cellular structure of bakery products. We have conducted a great number of studies and tests in our culinary labs. We have been able to produce an acceptable product—one which people would enjoy eating—under laboratory conditions, and now need to test it under a variety of settings and conditions to ensure that the product can be replicated with the same quality, stability and taste-profile throughout the United States, in different production settings, climates and altitudes.

Once we successfully test the trans fat-free oil, we have to source it from the companies that manufacture cooking oils. Sourcing is not a simple or quick proposition for Dunkin' Donuts. The 6,000-plus Dunkin' Donuts stores in the United States currently require a combined fifty-four million pounds of shortening (oil) annually. From the date of a successful test, it will take several months for any company to source the crops and begin to produce on the required scale. Further, Dunkin' Donuts will have to adjust its own supply chain once it is determined how the new oils will be delivered, in liquid or block form.

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Proposed Trans Fat Ban
Page Two
March 29, 2007

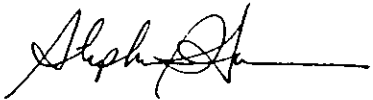
As I mentioned before, on December 5, 2006, the New York City Board of Health amended the city's health code to include a ban on the storage, distribution, and sale by restaurants of any food containing trans fat. The ban goes into effect as of July 1, 2007 for the use of oils, shortenings and margarines containing trans fat used in frying. However, based upon the particular issues associated with donuts and certain other baked goods, the NYC Board of Health extended until July 1, 2008 the deadline to replace artificial trans fat used in deep-frying the yeast doughs and cake batters that define donut products. I have attached a copy of the NYC Board of Health measure for your convenience.

We continue to work diligently to meet the July 2008 deadline set by the NYC Board of Health and, despite the challenges in front of us, we are confident we will meet it. We respectfully request that as part of your proposed measure, you set a similarly realistic deadline.

We would be most appreciative of your support. If you desire, we would welcome the opportunity to meet with you to further explain our challenges and our efforts.

Very truly yours,

Dunkin' Brands, Inc.



Stephen Horn
Legal Officer

SH/amd

Enclosure - Notice Of Adoption Of An Amendment (§81.08) To Article 81 Of The New York City Health Code

Cc: Councilmember Marilyn Praisner
Councilmember Phil Andrews
Councilmember Roger Berliner
Councilmember Marc Elrich
Councilmember Valerie Ervin
Councilmember Nancy Floreen
Councilmember Michael Knapp
Councilmember George Leventhal



028037

The Stop & Shop Supermarket Company LLC

**Giant Food LLC**

Barry F. Scher
Vice President
Public Affairs

8301 Professional Place
Suite 115
Landover, MD 20785
(301) 341-4710
FAX (301) 618-4967
bscher@aholdusa.com

April 24, 2007

The Honorable Duchy Trachtenberg
Montgomery County Council
100 Maryland Avenue
Rockville, Maryland 20850

Dear Ms. *Duchy* Trachtenberg:

We are writing to you in reference to your proposal to eliminate the use of artificial trans fats for cooking and food preparation purposes. We were under the impression that your bill would not affect full-service food stores but we are now not sure if this is the case. We believe that the Council should be very careful and clearly define in your definitions section when describing the types of business that fall under the proposed legislation. We do not believe your intent is for the bill to apply to food stores that sell ready-to-eat foods.

As you know from our long-standing commitment to area consumers, Giant indeed cares very much about health and good nutrition. There is much that we are doing on a voluntary basis to eliminate and reduce trans fat. We have worked with our suppliers to eliminate or reduce the amount of trans fats in products; we have expanded Nature's Promise, our private label line of natural and organic products, which are made without partially hydrogenated oils; we have switched the oil used for fried foods in our deli to zero trans fat frying oil; and we serve freshly prepared deli sandwiches with Nature's Promise natural meats and rotisserie chickens that are trans fat free. Our corporate brands purchasing staff is also working with our suppliers to reduce or eliminate trans fat in most products. We do get comments from shoppers regarding our bakery products - many of our items still use partially hydrogenated oils. We cannot make changes overnight but we are looking into this end of our business within bakery.

In conclusion, we feel that since the intent of your bill is aimed at the restaurant industry, the full-service retail food industry needs to be clearly defined so we are not impacted. We do know that customers want healthier foods and our voluntary goal is to do all we can to again, eliminate or reduce trans fat in our products.

Please let us know if you have any additional concerns. Our best wishes.

Sincerely,

Barry
Barry F. Scher

BFS:raa

cc: Montgomery County Council Members

(17)

RECEIVED
MONTGOMERY COUNTY
COUNCIL

2007 APR 25 AM 9:25



DIEM 10
#4

Madame President and Members of the Montgomery County Council, the Grocery Manufacturers/Food Products Association (GMA/FPA) respectfully opposes Council Resolution 16 banning trans fats.

GMA/FPA represents the world's leading food, beverage and consumer products companies. The association promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of the food supply through scientific excellence. The \$2.1 trillion food, beverage and consumer packaged goods industry employs 14 million workers, including over 10,000 employees at 49 facilities in Maryland.

GMA/FPA shares the Council's concerns for public health. In fact, through product reformulation and development of suitable alternatives by the food and beverage industry, trans fat in the food supply is decreasing.

However, to improve diet and health, and reduce cardiovascular disease, attention is required on dietary intake of *both* saturated and trans fat. Forcing the removal of all artificial trans fats from restaurant foods in Montgomery County by "January 1, 2008" as proposed in this resolution, could result in an increase of saturated fat in the food supply, as there is a very limited supply of trans fat free alternative oils.

The *2005 Dietary Guidelines for Americans* and other health authorities advise the public to focus on reducing overall intake of both saturated and trans fats as part of a nutritionally adequate diet and healthy lifestyle. In addition, research conducted in 2003 by the International Food Information Council found that overemphasizing a particular type of fat, such as trans fat, led consumers to disregard other components of the nutrition label such as saturated fat, cholesterol, and total fat content. The goal should be that dietary intake should reduce trans fat with no increase in the total of saturated plus prior trans fat level.

The collaboration between agriculture and food manufacturing has led to significant reductions of trans fat in food products over the past several years without a significant increase in saturated fat intake. However, the pace of future reformulations depends in large part upon the commercial availability of alternative fats and oils as well as the time needed to make and test product reformulations. Planting, harvesting, and processing new crops for fats and oils will take several years to meet the production demand of the entire food industry.

GMA/FPA urges the committee to consider the studied action taken by Los Angeles, California and Multnomah County, Oregon (Portland). These two jurisdictions are the first to undertake a comprehensive review the consequences of the New York City Board of Health ban, the agriculture and supply realities and the bans' unintended consequences. Los Angeles Policy makers decided upon a voluntary incentive program that will help phase out the use of trans fats in restaurant and foodservice locations. Portland officials decided upon a program to educate the public about trans fats. This approach allows for the flexibility needed to address the presence of trans fat in the food supply.

GMA/FPA urges the Council to oppose this resolution. Thank you for the opportunity to comment on this important issue.

1350 I Street, NW :: Suite 300 :: Washington, DC 20005 :: ph 202-639-5900 :: fx 202-639-5932

www.fpa-food.org

HHS

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April 26, 2007

028119

The Honorable George Leventhal
Councilman
Montgomery County Council
100 Maryland Avenue
Rockville, MD 20850

RECEIVED
MONTGOMERY COUNTY
COUNCIL

2007 APR 27 AM 9:31

Re: Trans Fat Resolution

Dear Councilman Leventhal:

After reviewing the resolution on the restrictions of the use of trans fats in eating and drinking establishments presented to the Montgomery County Council on April 24, 2007 the Maryland Retailers Association is in opposition to resolution as drafted. The Maryland Retailers Association whose membership includes the Maryland Food Dealers Council which represents the majority of the supermarkets and grocery stores that operate in and serve the citizens of Montgomery County are by definition, under Chapter 15 of the County Code, are included in this resolution.

The food industry has been working on a voluntary basis on the elimination of trans fats in the food items they sell and will continue this endeavor. The Maryland General Assembly also looked at this issue and decided to defer to the State Department of Health and Mental Hygiene to develop a plan for education of the dangers of trans fats and the reduction of them. This plan is to be finalized by the end of 2007 and the Maryland Retailers Association requests that the Montgomery County Council also defer to the DHMH. We also request that we be allowed to participate in any work sessions, including the one scheduled for 5/3/07 on this subject.

We thank you for your consideration of our requests.

Maryland Retailers Association

A handwritten signature in black ink, appearing to read "Jeffrie Zellmer", is written over a horizontal line. Below the signature is the printed name "Jeffrie Zellmer" and the title "Legislative Director".

Jeffrie Zellmer
Legislative Director

Cc: ☒ Montgomery County Council Members

(19)



TESTIMONY
RESTAURANT ASSOCIATION OF MARYLAND

Regulation of Artificial Trans Fats in Eating and Drinking Establishments

Madame President and Members of the Montgomery County Council:

The restaurant industry strongly supports phasing out the use of artificial trans fats (products containing more than 0.5 grams per serving) in the foods we serve. However, we oppose the current language of this proposed regulation because eliminating ALL artificial trans fats is simply impossible to accomplish in the short term. Instead, we support a gradual phase out with realistic timetables that consider the supply/demand problems with alternative products. The foodservice industry and public health officials should be working together to raise awareness, educate the public and encourage the industry to begin finding alternatives, with respect to supply, efficiency, cost, shelf life and the ultimate taste/texture of affected foods. Similar voluntary efforts are underway in both Baltimore City and Howard County.

Recently, the Maryland General Assembly rejected legislation to ban artificial trans fats (products containing more than 0.5 grams per serving) in foodservice facilities statewide. Instead, lawmakers have asked the Maryland Department of Health and Mental Hygiene (DHMH) to undertake the following activities: (1) examine efforts in other states and localities to assist restaurants in reducing trans fats; and (2) develop and implement a plan in which DHMH will educate or otherwise encourage restaurants to reduce trans fats. The legislature requested that DHMH present a plan to the Health and Government Operations Committee prior to the 2008 legislative session. We agree and commend the legislature for taking a more deliberative approach to addressing this issue. Until DHMH produces such a plan, we believe that local regulatory efforts are premature.

The bottom line right now is that there is an inadequate supply of available alternatives that provide healthier options at comparable cost, without changing the trademark quality and taste of the food products that our customers know and love. Some of our challenges are agricultural. More time is needed for the planting and harvesting of crops that can be effectively used for production of alternative oils. For example, farmers are not yet growing enough new soybean varieties (low in linolenic acid, which means that oils produced from these soybeans do not require hydrogenation to make them shelf stable) because the successful promotion of ethanol and biodiesel has made corn an excellent cash crop.

According to the Institute of Shortening and Edible Oils, the annual demand (including foodservice and food processing) for partially-hydrogenated oils subject to replacement (with trans fat-free alternatives) is about 8 billion pounds. However, the current supply of trans fat-free soy, canola, palm and other stable oils is only 4 billion pounds. Public officials simply cannot force industries to switch to alternatives when supplies are inadequate.

Compounding the supply challenge for many restaurants is the fact that larger national chains and food processors (Kraft, Frito-Lay, etc) have the buying power to enter into long-term contracts with oil suppliers, which only further diminishes the supply of alternatives for smaller restaurants. Moreover, smaller restaurants will likely be at an economic disadvantage with larger chains that will be able to lock into contracts that will allow them to maintain current menu price points. Smaller restaurants, however, will have no choice but to raise their menu prices to maintain the same profit margin in the wake of higher cost (currently 15-20% higher) trans fat-free cooking oils.

As food science makes progress, restaurants will gladly make the transition to healthier alternatives. However, prohibiting the use of trans fats before suitable alternatives are available may force the foodservice industry to use readily available products that contain no trans fats, but may be high in saturated fat. In New York City, for example, the American Heart Association opposed the trans fat ban, claiming that the ban may cause restaurants to revert to oils that are high in saturated fat. The heart association continues to caution consumers about trans fat-free products that may be high in saturated fat.

The lack of suitable alternatives has forced some companies to reluctantly turn back to palm oil, a saturated fat that was taken out of many products in the late 1980s. For example, Kraft Foods is using a combination of palm oil and high-oleic canola for the filling in its three trans fat-free Oreo varieties. According to Jean Spence, Kraft's executive vice president for technical quality, "getting the consistency that Oreo lovers expect without the firmness of palm oil would have been nearly impossible." The trade-off was an extra half-gram of saturated fat per serving. The company has not developed a method to make a proper tasting trans fat-free Oreo without increasing saturated fat levels.

Montgomery County bakeries and restaurants will face similar challenges when looking for trans fat-free alternatives for baking. While finding alternative frying oil is a challenge, finding alternatives for baking is an even greater challenge. Many restaurants no longer prepare their own desserts on-site. Instead, desserts and baked goods are often purchased from outside bakeries. Vegetable shortening, which contains artificial trans fat, is an important ingredient that contributes to the texture and taste of many baked goods. Shortening is essential for a flaky pie crust, as baking is more about chemistry than any other type of cooking. Consequently, it will not be easy to find baking alternatives that perform well and do not change the taste, texture and quality of the finished product.

While Crisco recently announced a reformulated trans fat-free product that should be suitable for many baking applications, the current distribution is limited to retail sales only (not commercial). Once the product becomes available commercially, bakeries must conduct extensive testing and reformulation of their own recipes in order to maintain consistent quality and taste. Without suitable alternatives, many bakeries will likely switch to butter (which is high in saturated fat) until more options become available.

We have recently been in touch with three major foodservice suppliers (Sysco, US Foodservice, Saval Foods) to check the availability of trans fat-free products (other than frying oil). None of these suppliers offers a full line of trans fat-free products (less than 0.5 grams per serving) to comply with the proposed ban. One supplier said that they would not be able to meet the needs of Montgomery County restaurants unless the restaurants were willing to design menus around product availability. Another supplier said that they have only recently started to identify trans fat-free products among their current offerings and estimates that less than 10 percent of their current products (that contain fats) are completely trans fat-free (less than 0.5 grams per serving). Contrary to what we all want to believe, the supply problem is a huge hurdle that will be difficult to overcome in the short term.

I. BACKGROUND

Restaurants are actively working to reduce the amount of trans fat on their menus. At the same time, the industry faces several obstacles in trans fat reduction, including: the lack of available alternatives, improving technology to produce adequate alternatives, and the costs associated with a change in product formulation.

Trans fatty acids (trans fats) are the bi-product of cooking or producing food with partially-hydrogenated oils. They are used in processed foods because they produce high-quality food products that are able to stay fresh for longer periods of time. It is not always possible to substitute non-hydrogenated oils in their place because of differences in the way that the oils are able to produce food products that maintain flavor.

Commercial production of partially-hydrogenated fats began in the early 20th century and increased until the late 1960s as processed vegetable fats began to displace animal fats in the diets of U.S. and other Western Countries. This displacement was due to a variety of reasons, including what were – at the time – viewed as “health benefits.” When it was discovered that saturated fats have adverse effects on blood lipids, the restaurant industry took its guidance from the science and health industries, which sought to limit or cut the consumption of these fats.

Restaurants – searching for a new alternative – began to use partially-hydrogenated vegetable oils in lieu of animal fats (beef tallow, lard, and butter) in the late 1970s and early 1980s. As a result, many restaurants now use pure vegetable oil or a blend of vegetable and animal fat oils (many of which contain artificial trans fats).

II. FACTS AT-A-GLANCE

What are artificial trans fats?

Artificial trans fats are unsaturated fatty acids that are formed when vegetable oils are processed and made more stable by a process called hydrogenation. Trans unsaturated fatty acids, or trans fats, are solid fats that are produced by heating liquid vegetable oils in the presence of metal catalysts and hydrogen.

What are the major sources of artificial trans fats in the American diet?

Artificial trans fat is found in vegetable shortenings, some margarines, crackers, candies, cookies, snack foods, fried foods, baked goods, and other processed foods made with partially-hydrogenated vegetable oils. Trans fats naturally occur in foods including: butter, milk products, beef, lamb and cheese.

Although trans fats and saturated fats both increase levels of bad cholesterol in the body, recent science shows that artificial trans fats NOT ONLY increase bad cholesterol, BUT ALSO lower good cholesterol. For this reason, many health experts believe that artificial trans fats are worse. New York City and Philadelphia are the only jurisdictions to ban artificial trans fats in restaurants so far. However, similar proposals are pending nationwide.

III. CHALLENGES FOR FOOD INDUSTRY

The food industry is market driven and is constantly researching and developing products and formulations that will meet the tastes and preferences of its consumers. Many food companies – in their commitment to promoting healthy lifestyles – have taken steps to reduce or eliminate the amount of hydrogenated oils in their products. For example, Legal Seafoods, Ruby Tuesday Restaurants, Quiznos,

Au Bon Pain, KFC and Wendy's are just a few of the national chains that have eliminated or are in the process of eliminating trans fats from their menus. However, challenges remain.

Availability and Technology

Trans fat-free oils are simply not available in mass quantities at the present time. Currently, there is not a large enough supply of any one seed/bean to produce enough trans-fat-free oil to be used world-wide – creating a major challenge for farmers (particularly soy bean farmers) and food chemists. While scientists and farmers are working hard to develop and plant new types of soybeans and alternative crops that will either reduce or eliminate trans fats in processed oils, these products will not be available in mass quantities for at least several years.

In 2004, major agribusiness companies, including Dow AgroSciences, Bunge and DuPont, all launched various brands of zero- or low-trans fat oil. They join Archer Daniels Midland, which previously developed the *NovaLipid* line of zero- and low-trans fat oils (a blend of sunflower, soy, and cottonseed oil). Yet, none of these companies is able to produce the mass quantities needed to satisfy demand.

Bunge Limited and DuPont (in addition to its subsidiary, Pioneer) have announced the development of soybeans that are low in linolenic acid – which means that they do not require hydrogenation for use. Currently, only limited quantities of the oil are available for use in product development and testing. Bunge expects to gradually increase production over the next several years and hopes to have full-scale commercial availability (nearly 1 billion pounds) by 2009.

Conclusion

The restaurant industry has been responding to concerns about fats for many years. It is important to note that our industry did not need legislative/regulatory prohibitions in the 1980s when we abandoned lard or beef tallow and switched to partially-hydrogenated oils for frying, which everyone believed to be healthier at the time. The industry will once again make a major transition when new alternatives become readily available. However, hastily banning artificial trans fats without giving the issue proper study or time is certainly the wrong approach.

Respectfully submitted,

Date: 04/24/07



Melvin R. Thompson
Vice President - Government Relations

STEVE F. DE CASTRO BUILDING
6301 HILLSIDE COURT
COLUMBIA, MD 21046-1048

TELEPHONE: 410-290-6800

FACSIMILE: 410-290-6882

www.marylandrestaurants.com

attachments: 5

The following issues should be addressed in the language of Montgomery County's proposed regulation of Artificial Trans Fats in Eating and Drinking Establishments:

1. Under the Definitions section of this proposal, the term "Eating and Drinking Establishment" should be clearly defined. In other areas of this proposed regulation, compliance is enforced by the Department of Health and Human Services, under Chapter 15 of the County Code. The following definition is taken directly from Montgomery County Code:
 - (d) ***Eating and drinking establishment: Any food service facility.***
 - (f) ***Food service facility: Any enterprise that prepares or sells food or drink for human consumption on or off the premises. Food service facility includes:***
 - (1) ***Any restaurant, coffee shop, retail market, cafeteria, short-order cafe, luncheonette, tavern, sandwich stand, soda fountain; and***
 - (2) ***Any food service facility in an industry, institution, hospital, club, school, church, catering kitchen, or camp.***
2. Under this definition, the ban on trans fats would also include the foodservice portion of grocery stores that sell prepared ready-to-eat foods at salad and hot food bars. Snack bars at bowling alleys, sporting facilities and health clubs are also regulated under Chapter 15. Moreover, movie popcorn (long a trans fat culprit) sold at theaters would also be included in such a ban. Schools, hospitals, churches and clubs are also included. To be fair and equitable, this only makes sense if such a regulation is approved to protect public health. Temporary Foodservice Facility Licenses that are issued for County fairs, festivals and other special events are also regulated under Chapter 15 and could also be included to protect public health.
3. Councilwoman Trachtenberg has said, on more than one occasion, that her intent is to regulate the trans fat content of ONLY those food items that are prepared on-site. If this is true, the language of the proposed regulation needs to be changed to reflect this intent. Under the current language, ONLY foods that are "*served directly to patrons in the manufacturer's original sealed package*" are exempt. For example, chips, crackers, muffins, danishes and other such products that contain more than 0.5 grams of trans fat per serving are exempt if served in original packaging. However, if a muffin is removed from the package and served on a plate along with fresh fruit, for example, the foodservice establishment would be in violation.

4. If the intent is to regulate only those products that are prepared on-site, some consideration should be given to products that are purchased ready-to-cook. For example, many frozen French fries, onion rings, curly fries, chicken nuggets/patties, mozzarella sticks, jalapeno poppers, and other such products are pre-blanching or coated with breading or other ingredients that contain artificial trans fats. It would be difficult, if not impossible, to replace these items without cooperation from manufacturers, which would likely take considerable time. In addition, boxed and refrigerated mixes and batters (which reduce the labor and inconsistency problems associated with making such products from scratch) would also be impossible to replace without cooperation from manufacturers. Likewise, many restaurants no longer prepare their own desserts on-site. Cakes, pies, cookies, cheesecakes and other dessert items are often purchased from wholesale suppliers (outside of Montgomery County). It is impossible for Montgomery County establishments to control the ingredients of these products.
5. Most chain restaurants have no flexibility in the products they use. Many of the food products they serve are specified and/or supplied through corporate headquarters. Local compliance for these establishments would require corporate changes.
6. Replacing shortenings and partially-hydrogenated oils in baked goods and other foods present far more challenges than replacing these ingredients in oils used for frying. Both New York City and Philadelphia recognized these challenges and established later effective dates to compensate. Montgomery County's proposal makes no such distinction.
7. Nationwide, chain restaurants and wholesale foodservice suppliers are scrambling to make the necessary changes to comply with recent citywide frying oil regulations (effective July 2007 in New York City and September 2007 in Philadelphia). Efforts are also underway to make the changes necessary to comply with recent citywide regulations for baked products and other foods (effective July 2008 in New York and September 2008 in Philadelphia). Despite these effective dates, no one can accurately predict unforeseen compliance issues. If the Montgomery County Council insists on approving such a regulation, it should consider effective dates that are later than the dates for these cities to avoid problems and insure broader compliance. July 2009 (one year after the final phase of New York City's incremental approach) would be more appropriate.
8. Under the Enforcement section of this proposal, the Health Department may suspend, for up to three days, the license of an Eating and Drinking Establishment that knowingly and repeatedly violates this regulation. This seems unnecessarily punitive and does not take into consideration relatively common instances when an establishment is forced to accept a substitute food product from a supplier because the trans fat-free version may be out of stock.

For more information or additional comments, call Melvin Thompson at the Restaurant Association of Maryland at 410-290-6800.



Dr Dana Beyer

Subject: - No Trans Fat Oils and the availability

Frying oils containing No Trans Fats have increased in popularity with the required labeling law, mandated back in January 2006. Large restaurant chains have been reluctant to switch because they have been told by the larger processor that there is not enough supply to meet the need.

Their answer to the problem is to generically modify the soybean to breed out the Omega 3 essential fatty acids, also known as Linolenic acid. This component of the soybean has been with the current extraction process, very detrimental to the shelf life of the oil. Hydrogenation which causes Trans Fats was created to give oil shelf life and fry life. This process however destroys the Linolenic acids and makes the oil more stable but less healthy. Therefore to breed this out would yield oil that would not have to be hydrogenated which equals Trans Fats. With this process, it could take seven to nine years to get enough soybeans grown and produced into oil to meet the demand.

So the alternative is to look at the NT Blends that are already available. They cost more than most hydrogenated oils but have the performance to offset the difference in price. There is a good supply of these oils available as well as just using a basic salad oil (non hydrogenated soybean oil) for frying. Salad oil will not last as long, but also is No Trans.

Whole Harvest, which is a 100% soybean oil, uses a mechanical press process (no chemicals) for the extraction. This process along with natural refining yields an oil with performance, high in Linolenic acids, high in vitamin E and No Trans Fats. With this process (which is patented) there is no need for the soybean modification. Quality NO Trans Oils can be supplied now. Whole Harvest alone has approximately 60 million lbs per year, available now. So you see, No Trans oils are available, a process is available, it's just the larger processors, don't want it known until they can supply it with their product!

Bob Dawson
COO
Whole Harvest LLC

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Carolina Soy Products, LLC

PO Box 527 • 376 Westpark Drive • Warsaw, NC 28398 • Office: 910.293.7917 • Fax: 910.293.7918
www.wholeharvest.com



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This article contains revisions made in September 2005.

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Revealing *Trans* Fats

Scientific evidence shows that consumption of saturated fat, *trans* fat, and dietary cholesterol raises low-density lipoprotein (LDL), or "bad cholesterol," levels, which increases the risk of coronary heart disease (CHD). According to the National Heart, Lung, and Blood Institute of the National Institutes of Health, more than 12.5 million Americans have CHD, and more than 500,000 die each year. That makes CHD one of the leading causes of death in the United States.

The Food and Drug Administration has required that saturated fat and dietary cholesterol be listed on food labels since 1993. Starting Jan. 1, 2006, listing of *trans* fat will be required as well. With *trans* fat added to the Nutrition Facts panel, required by Jan. 1, 2006, you will know for the first time how much of all three—saturated fat, *trans* fat, and cholesterol—are in the foods you choose. Identifying saturated fat, *trans* fat, and cholesterol on the food label gives you information you need to make food choices that help reduce the risk of CHD. This revised label will be of particular interest to people concerned about high blood cholesterol and heart disease.

However, everyone should be aware of the risk posed by consuming too much saturated fat, *trans* fat, and cholesterol. But what is *trans* fat, and how can you limit the amount of this fat in your diet?

What is *Trans* Fat?

Basically, *trans* fat is made when manufacturers add hydrogen to vegetable oil—a process called hydrogenation. Hydrogenation increases the shelf life and flavor stability of foods containing these fats.

Trans fat can be found in vegetable shortenings, some margarines, crackers, cookies, snack foods, and other foods made with or fried in partially hydrogenated oils. Unlike other fats, the majority of *trans* fat is formed when food manufacturers turn liquid oils into solid fats like shortening and hard margarine. A small amount of *trans* fat is found naturally, primarily in some animal-based foods.

Trans fat, like saturated fat and dietary cholesterol, raises the LDL cholesterol that increases your risk for CHD. Americans consume on average 4 to 5 times as much saturated fat as *trans* fat in their diets.

Although saturated fat is the main dietary culprit that raises LDL, *trans* fat and dietary cholesterol also contribute significantly.

Are All Fats the Same?

Simply put: No. Fat is a major source of energy for the body and aids in the absorption of vitamins A, D, E, and K and

Major Food Sources of *Trans* Fat for American Adults

(Average Daily *Trans* Fat
Intake is 5.8 Grams or 2.6
Percent of Calories)

40%

cakes, cookies, crackers,
pies, bread, etc.

21%

animal products

17%

margarine

8%

fried potatoes

5%

carotenoids. Both animal- and plant-derived food products contain fat, and when eaten in moderation, fat is important for proper growth, development, and maintenance of good health. As a food ingredient, fat provides taste, consistency, and stability and helps you feel full. In addition, parents should be aware that fats are an especially important source of calories and nutrients for infants and toddlers (up to 2 years of age), who have the highest energy needs per unit of body weight of any age group.

While unsaturated fats (monounsaturated and polyunsaturated) are beneficial when consumed in moderation, saturated and *trans* fats are not. Saturated fat and *trans* fat raise LDL cholesterol levels in the blood. Dietary cholesterol also contributes to heart disease. Therefore, it is advisable to choose foods low in saturated fat, *trans* fat, and cholesterol as part of a healthful diet.

What Can You Do About Saturated Fat, *Trans* Fat, and Cholesterol?

When comparing foods, look at the Nutrition Facts panel, and choose the food with the lower amounts of saturated fat, *trans* fat, and cholesterol. Health experts recommend that you keep your intake of saturated fat, *trans* fat, and cholesterol as low as possible while consuming a nutritionally adequate diet. However, these experts recognize that eliminating these three components entirely from your diet is not practical because they are unavoidable in ordinary diets.

potato chips, corn chips,
popcorn

4%

household shortening

3%

salad dressing

1%

breakfast cereal

1%

candy

Data based on FDA's economic analysis for the final *trans* fatty acid labeling rule, "Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims" (July 11, 2003)

Where Can You Find *Trans* Fat on the Food Label?

Beginning in January 2006 food manufacturers must list *trans* fat on all their products.

You will find *trans* fat listed on the Nutrition Facts panel directly under the line for saturated fat.

How Do Your Choices Stack Up?

With the addition of *trans* fat to the Nutrition Facts panel, you can review your food choices and see how they stack up. (See the table illustrating total fat, saturated fat, *trans* fat, and cholesterol content per serving for selected food products.)

Don't assume similar products are the same. Be sure to check the Nutrition Facts panel because even similar foods can vary in calories, ingredients, nutrients, and the size and number of servings in a package. Even if you continue to buy the same brand of a product, check the Nutrition Facts panel frequently because ingredients can change at any time.

Total Fat, Saturated Fat, *Trans* Fat, and Cholesterol Content Per Serving*

Product	Common Serving Size	Total Fat g	Sat. Fat g	%DV for Sat. Fat	<i>Trans</i> Fat g	Combined Sat. & <i>Trans</i> Fat g	Chol. mg	%DV for Chol.
French Fried Potatoes± (Fast Food)	Medium (147 g)	27	7	35%	8	15	0	0%
Butter**	1 tbsp	11	7	35%	0	7	30	10%
Margarine, stick†	1 tbsp	11	2	10%	3	5	0	0%
Margarine, tub†	1 tbsp	7	1	5%	0.5	1.5	0	0%

Mayonnaise†† (Soybean Oil)	1 tbsp	11	1.5	8%	0	1.5	5	2%
Shortening±	1 tbsp	13	3.5	18%	4	7.5	0	0%
Potato Chips±	Small bag (42.5 g)	11	2	10%	3	5	0	0%
Milk, whole±	1 cup	7	4.5	23%	0	4.5	35	12%
Milk, skim†	1 cup	0	0	0%	0	0	5	2%
Doughnut±	1	18	4.5	23%	5	9.5	25	8%
Cookies± (Cream Filled)	3 (30 g)	6	1	5%	2	3	0	0%
Candy Bar±	1 (40 g)	10	4	20%	3	7	<5	1%
Cake, pound±	1 slice (80 g)	16	3.5	18%	4.5	8	0	0%

*Nutrient values rounded based on FDA's nutrition labeling regulations.

** Butter values from FDA Table of *Trans* Values, 1/30/95.

† Values derived from 2002 USDA National Nutrient Database for Standard Reference, Release 15.

†† Prerelease values derived from 2003 USDA National Nutrient Database for Standard Reference, Release 16.

± 1995 USDA Composition Data.

How Can You Use the Label to Make Heart-Healthy Food Choices?

The Nutrition Facts panel can help you choose foods lower in saturated fat, *trans* fat, and cholesterol. Compare similar foods and choose the food with the lower combined saturated and *trans* fats and the lower amount of cholesterol.

Although the updated Nutrition Facts panel will list the amount of *trans* fat in a product, it will not show a Percent Daily Value (%DV). While scientific reports have confirmed the relationship between *trans* fat and an increased risk of CHD, none has recommended an amount of *trans* fat that the FDA could use to establish a Daily Value or a %DV.

There is, however, a %DV shown for saturated fat and cholesterol. To choose foods low in saturated fat and cholesterol, use the general rule of thumb that 5 percent of the Daily Value or less is low and 20 percent or more is high.

You can also use the %DV to make dietary trade-offs with other foods throughout the day. You don't have to give up a favorite food to eat a healthy diet. When a food you like is high in any of these cholesterol-raising components, balance it with foods that are low in them at other times of the day.

Do Dietary Supplements Contain *Trans* Fat?

Would it surprise you to know that some dietary supplements contain *trans* fat from partially hydrogenated vegetable oil as well as saturated fat or cholesterol? It's true. As a result of the FDA's new label requirement, if a dietary supplement contains a reportable amount of *trans* or saturated fat, which is 0.5 gram or more, dietary supplement manufacturers must list the amounts on the Supplement Facts panel. Some dietary supplements that may contain saturated fat, *trans* fat, and cholesterol include energy and nutrition bars.

Fat Tips

Here are some practical tips you can use every day to keep your consumption of saturated fat, *trans* fat, and cholesterol low while consuming a nutritionally adequate diet.

- Check the Nutrition Facts panel to compare foods because the serving sizes are generally consistent in similar types of foods. Choose foods lower in saturated fat, *trans* fat, and cholesterol. For saturated fat and cholesterol, keep in mind that 5 percent of the Daily Value (% DV) or less is low and 20 percent or more is high. (There is no %DV for *trans* fat.)
 - Choose alternative fats. Replace saturated and *trans* fats in your diet with monounsaturated and polyunsaturated fats. These fats do not raise LDL cholesterol levels and have health benefits when eaten in moderation. Sources of monounsaturated fats include olive and canola oils. Sources of polyunsaturated fats include soybean oil, corn oil, sunflower oil and foods like nuts.
 - Choose vegetable oils (except coconut and palm kernel oils) and soft margarines (liquid, tub, or spray) more often because the combined amount of saturated fat and *trans* fat is lower than the amount in solid shortenings, hard margarines, and animal fats, including butter.
 - Consider fish. Most fish are lower in saturated fat than meat. Some fish, such as mackerel, sardines, and salmon, contain omega-3 fatty acids, which are being studied to determine if they offer protection against heart disease.
 - Choose lean meats, such as poultry without the skin and not fried and lean beef and pork, not fried, with visible fat trimmed.
 - Ask before you order when eating out. A good tip to remember is to ask which fats are being used in the preparation of your food when eating or ordering out.
 - Limit foods high in cholesterol such as liver and other organ meats, egg yolks, and full-fat dairy products, like whole milk.
 - Choose foods low in saturated fat such as fat free or 1% dairy products, lean meats, fish, skinless poultry, whole grain foods, and fruits and vegetables.
-

Highlights of the Final Rule on *Trans* Fat

- Manufacturers of conventional foods and some dietary supplements are required to list *trans* fat on a separate line, immediately under saturated fat on the nutrition label.
 - Food manufacturers have until Jan. 1, 2006, to list *trans* fat on the nutrition label.
 - FDA's regulatory chemical definition for *trans* fatty acids is all unsaturated fatty acids that contain one or more isolated (i.e., nonconjugated) double bonds in a *trans* configuration. Under the Agency's definition, conjugated linoleic acid would be excluded from the definition of *trans* fat.
 - Dietary supplement manufacturers must also list *trans* fat on the Supplement Facts panel when their products contain reportable amounts (0.5 gram or more) of *trans* fat. Examples of dietary supplements with *trans* fat are energy and nutrition bars.
-

For More Information

[Questions and Answers on the *Trans* Fat Final Rule](#)

[Backgrounder: FDA Acts to Provide Better Information to Consumers on Trans Fats](#)

[Guidance on How to Understand and Use the Nutrition Facts Panel on Food Labels](#)

[Quiz--Test Your Food Label Knowledge](#)

[Federal Register Final Rule: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims](#)

[Advance Notice of Proposed Rulemaking to solicit information on *trans* fat nutrient and health claims](#)

[Trans Fat Now Listed with Saturated Fat and Cholesterol on the Nutrition Facts Label](#)

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Federal Register

Friday,
July 11, 2003

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 101

**Food Labeling; Trans Fatty Acids in
Nutrition Labeling; Consumer Research to
Consider Nutrient Content and Health
Claims and Possible Footnote or
Disclosure Statements; Final Rule and
Proposed Rule**

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 94P-0036]

RIN 0910-AB66

Food Labeling: *Trans* Fatty Acids in
Nutrition Labeling, Nutrient Content
Claims, and Health ClaimsAGENCY: Food and Drug Administration,
HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations on nutrition labeling to require that *trans* fatty acids be declared in the nutrition label of conventional foods and dietary supplements on a separate line immediately under the line for the declaration of saturated fatty acids. This action responds, in part, to a citizen petition from the Center for Science in the Public Interest (CSPI). This rule is intended to provide information to assist consumers in maintaining healthy dietary practices. Those sections of the proposed rule pertaining to the definition of nutrient content claims for the "free" level of *trans* fatty acids and to limits on the amounts of *trans* fatty acids wherever saturated fatty acid limits are placed on nutrient content claims, health claims, and disclosure and disqualifying levels are being withdrawn. Further, the agency is withdrawing the proposed requirement to include a footnote stating: "Intake of *trans* fat should be as low as possible." Issues related to the possible use of a footnote statement in conjunction with the *trans* fat label declaration or in the context of certain nutrient content and health claims that contain messages about cholesterol-raising fats in the diet are now the subject of an advance notice of proposed rulemaking (ANPRM) which is published elsewhere in this issue of the *Federal Register*.

DATES: This rule is effective January 1, 2006.

FOR FURTHER INFORMATION CONTACT: Julie Schrimpf, Center for Food Safety and Applied Nutrition (HFS-832), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2373.

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I. Background

A. Nutrition Labeling

The Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Public Law 101-535) amended the Federal Food, Drug, and Cosmetic Act (the act) to provide, among other things, that certain nutrients and food components be included in nutrition labeling. Section 403(q)(2)(A) and (q)(2)(B) (21 U.S.C. 343(q)(2)(A) and (q)(2)(B)) of the act state that the Secretary of Health and Human Services (the Secretary) (and, by delegation, FDA) can, by regulation, add or delete nutrients included in the food label or labeling if he or she finds such action

necessary to assist consumers in maintaining healthy dietary practices.

In response to these provisions, in the *Federal Register* of November 27, 1991 (56 FR 60366), FDA published a proposed rule entitled "Food Labeling: Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrient Content Revision." In that document, the agency proposed to require that foods bear nutrition labeling listing certain nutrients and the amount of those nutrients in a serving of the food. Given the scientific knowledge about *trans* fatty acids at the time, FDA did not propose to require that *trans* fatty acids be listed. However, FDA requested comments on whether the listing of *trans* fatty acids should be voluntary (56 FR 60366 at 60371). (Note: throughout this preamble, FDA has used the term "*trans* fatty acids" and "*trans* fat" interchangeably; likewise, for the terms "saturated fatty acids," and "saturated fat").

In the *Federal Register* of January 6, 1993 (58 FR 2079), FDA issued a final rule implementing the 1990 amendments entitled "Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label" that prescribes how nutrition labeling is to be provided on foods that are regulated by the agency. In that document, the agency required the declaration of total fat and saturated fat in the nutrition label, with the declaration of both monounsaturated fat and polyunsaturated fat (both defined as the *cis* isomers only) required, when claims are made about fatty acids and cholesterol. Based on its review of the comments, the agency stated that it was premature to include *trans* fatty acids in nutrition labeling because of a lack of agreement on the dietary implications of *trans* fatty acid intake. However, the agency acknowledged that it might be necessary to revisit the labeling of *trans* fatty acids in the future (58 FR 2079 at 2090-2092).

FDA received a citizen petition, dated February 14, 1994, from CSPI (docket number 94P-0036/CP1) stating that an increasing body of evidence suggests that dietary *trans* fatty acids raise blood cholesterol levels, thereby increasing the risk of coronary heart disease (CHD). The petitioner argued that the 1993 final rules implementing the 1990 amendments do not adequately reflect the effect of dietary *trans* fatty acids on CHD and that label values for saturated fat underestimate the total amount of "heart-unhealthy" fats because *trans* fatty acids are not declared. CSPI requested that FDA amend the definition of saturated fat in

§ 101.9(c)(2)(i) (21 CFR 101.9(c)(2)(i)) to include *trans* fatty acids so that the declaration of saturated fat on the nutrition label would provide consumers with complete information on all "heart-unhealthy" fatty acids. In addition, the petitioner requested that all saturated fat claims in § 101.62(c) (21 CFR 101.62(c)), the saturated fat threshold on all cholesterol claims in § 101.62(d), the claims for "lean" and "extra lean" in § 101.62(e), and disqualification and disclosure levels for health and nutrient content claims be amended to reflect the combined levels of saturated and *trans* fatty acids. Further, CSPI requested that FDA: (1) Limit "vegetable oil" claims (e.g., "made with vegetable oil") to foods that are low in both saturated and *trans* fatty acids, and (2) require that "partially hydrogenated" fat be listed on food labels as "partially saturated."

On July 13, 1998, CSPI amended its petition in a way that would maintain the definition of saturated fat in § 101.9(c)(2)(i), yet provide consumers with information on the *trans* fatty acid content of the food. Specifically, CSPI suggested that FDA either: (1) Disclose the sum of *trans* and saturated fats next to the term "saturated fat*" with an asterisk at the bottom of the label that states "contains ___ grams of *trans* fat," or (2) disclose the sum of *trans* and saturated fats next to the term "saturated + *trans* fat" when *trans* fat was present.

In response to CSPI's petition, FDA issued a proposed rule in the **Federal Register** of November 17, 1999 (64 FR 62746), entitled "Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims" (hereinafter identified as "the November 1999 proposal"). In that document, FDA proposed to amend its nutrition labeling regulations to require that the amount of *trans* fatty acids in a food, including dietary supplements, be included in the amount and percent Daily Value (%DV) declared for saturated fatty acids, with a footnote indicating the amount of *trans* fatty acids in a serving of the product, when the product contains 0.5 or more grams (g) *trans* fatty acids per serving. FDA reviewed recent research that showed that consumption of diets containing *trans* fatty acids, like diets containing saturated fats, results in increased serum low-density lipoprotein cholesterol (LDL-C), a major risk factor for CHD. The proposed rule was issued to assist consumers in maintaining healthy dietary practices (64 FR 62746 at 62754).

B. Nutrient Content and Health Claims

In the **Federal Register** of November 27, 1991 (56 FR 60478), FDA also published a proposed rule entitled "Food Labeling: Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food." Although the agency proposed definitions for fat, fatty acid, and cholesterol nutrient content claims, it did not propose a definition for the nutrient content claim "saturated fat free." However, the comments in response to that proposal recommended that FDA define the claim "saturated fat free."

In the **Federal Register** of January 6, 1993 (58 FR 2302), FDA issued a final rule entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definition of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food," (hereinafter the "nutrient content claims final rule"). In that rule, the agency stated that it did not set a *trans* fat criterion for most claims because the evidence suggesting that *trans* fatty acids raise serum cholesterol was inconclusive at that time (58 FR 2302 at 2332 and 2340). However, FDA did set a *trans* fat criterion for the "saturated fat free" claim stating that "because of the uncertainty regarding this issue, the fact that consumers would expect a food bearing a 'saturated fat free' claim to be free of saturated fat and other components that significantly raise serum cholesterol, and the potential importance of a saturated fat free claim, the agency believes that it would be misleading for products that contain measurable amounts of *trans* fatty acids to bear a 'saturated fat free' claim" (58 FR 2302 at 2332). The *trans* fat criterion for the claim "saturated fat free" was set at a level not to exceed 1 percent of total fat in the food (58 FR 2302 at 2419). The agency stated that 1 percent was the appropriate threshold because analytical methods for measuring *trans* fatty acids below that level were not reliable (58 FR 2302 at 2332). This action was taken under the authority of section 403(r)(2)(A)(vi) of the act, which prohibits a claim if it is misleading in light of the level of another nutrient in the food.

Some comments that FDA received after publication of the nutrient content claims final rule objected to the 1 percent criterion for *trans* fatty acids in the definition of "saturated fat free." One comment pointed out that a cookie containing 1.5 g of total fat would be allowed to have only 0.015 g of *trans* fatty acids, an amount that could not be

accurately measured. In response to these comments, in the **Federal Register** of August 18, 1993 (58 FR 44020 at 44032), the agency amended the definition of "saturated fat free" to require that a food contain less than 0.5 g of *trans* fatty acids in addition to less than 0.5 g of saturated fat per reference amount customarily consumed (hereinafter referred to as "reference amount") and per labeled serving to be eligible to bear the claim.

In the November 1999 proposal, FDA concluded that dietary *trans* fatty acids have adverse effects on blood cholesterol measures that are predictive of CHD risk (64 FR 62746 at 62754). Consequently, to avoid misleading claims, the agency proposed that the amount of *trans* fatty acids be limited wherever saturated fat limits are placed on nutrient content claims, health claims, or disclosure and disqualifying levels. In the November 1999 proposal, the agency did not propose to take action requested by CSPI to amend § 101.65(c)(3) (21 CFR 101.65(c)(3)) to state that "made with vegetable oil" is an implied claim that the product is low in saturated fat and *trans* fats combined (64 FR 62746 at 62762) because the agency proposed to amend nutrient content claims for saturated fat to include a *trans* fatty acid criterion. The agency stated that the proposed amendments to nutrient content claims and the requirements for implied nutrient content claims in § 101.65(c)(3) adequately addressed the petitioner's request.

In addition, in the November 1999 proposal, FDA requested comment on whether "trans fat free" claims would help consumers maintain healthy dietary practices and whether they would provide incentive to the food industry to reduce the amount of *trans* fat in the food supply (64 FR 62746 at 62759). FDA proposed a definition for the *trans* fat free claim. FDA concluded that there was no basis for defining "low *trans* fat" without quantitative recommendations for daily intake of *trans* fat. Further, FDA did not define a "reduced *trans* fat" claim because it was concerned that a reduced *trans* fat claim would detract from educational messages that emphasize lower intakes of saturated fat. Persons who believed that a "reduced *trans* fat" claim would be useful were advised to submit a petition under § 101.69 (21 CFR 101.69).

In the November 1999 proposal, FDA proposed to deny CSPI's request that the agency require that "partially hydrogenated" fat be listed as "partially saturated" fat (64 FR 62746 at 62762). Among other reasons, the agency stated that "hydrogenated" and "partially

hydrogenated" are not intended to describe the nutritional properties of the fat or oil. It explained that the purpose of the ingredient statement is to identify the ingredients in a food by listing the common or usual names of each ingredient (64 FR 62746 at 62762–62763).

Comments to the November 1999 proposal requested that the final rule define the nutrient content claim "reduced *trans* fat." Other comments suggested a "reduced saturated fat" claim that would be defined as a reduction of saturated and *trans* fats combined. The agency considered these comments and determined that all interested parties should have an opportunity to comment on whether the final rule should define claims that address reduced levels of *trans* fat. Therefore, FDA reopened the comment period for the November 1999 proposal on December 5, 2000, for a period of 45 days (65 FR 75887) stating that it would consider only comments that addressed "reduced *trans* fat" and "reduced saturated and *trans* fat" claims.

Subsequent to FDA's November 1999 proposal, the Institute of Medicine of the National Academy of Sciences (IOM/NAS) issued a report entitled "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids" (the IOM/NAS macronutrient report) (Ref. 140) and found, similar to the effect of saturated fat, "a positive linear trend" between *trans* fatty acid intake and total and LDL-C concentrations, and therefore increased risk of CHD. Because *trans* fats are unavoidable in ordinary diets, the IOM/NAS report recommended that "*trans* fat consumption be as low as possible while consuming a nutritionally adequate diet." Likewise, the conclusions in two other scientific reports, which became available subsequent to the November 1999 proposal, i.e., the Dietary Guidelines for Americans, 2000 (Ref. 88) and guidelines from the National Cholesterol Education Program (NCEP) (Ref. 89), were similar with recommendations to limit *trans* fat intake in the diet. Although the IOM/NAS report (Ref. 140) underscored the relationship between the intake of *trans* fat and the increased risk for heart disease and emphasized that consumers need to limit *trans* fat in their diets, it did not provide a Dietary Reference Intake (DRI) value for *trans* fat or information that FDA believes is sufficient to support the agency's establishing a Daily Reference Value (DRV) or other information on the label, such as a %DV, for *trans* fat.

In response to the recommendations of the new scientific reports to limit the intake of *trans* fat and to provide consumers with label information that may better assist them in understanding the quantitative declaration of *trans* fat in the context of a total daily diet, FDA reopened the comment period of the November 1999 proposal for a period of 30 days (67 FR 69171, November 15, 2002). In that document the agency proposed to require an asterisk (or other symbol) in the %DV column for *trans* fat, when it is listed, that is tied to a similar symbol at the bottom of the Nutrition Facts box that is followed by the statement "Intake of *trans* fat should be as low as possible." The agency stated that the statement is taken from the IOM/NAS macronutrient report and is consistent with the dietary guidance in the other recent scientific reports identified in that document (67 FR 69171 at 69172).

In the November 15, 2002, **Federal Register** document to reopen the comment period the agency also stated that it would consider the exercise of its enforcement discretion for those manufacturers who wanted to begin labeling the *trans* fat content of food products prior to publication of the final rule (67 FR 69171 at 69172). The agency cautioned manufacturers that the *trans* fat final rule may differ from what was being proposed in the November 15, 2002, document to reopen the comment period and that manufacturers would then be required to change their labels to conform to the final rule.

C. Comments

FDA received over 1,650 letters in response to the November 1999 proposal, over 45 letters in response to the December 5, 2000, notice reopening the comment period, and over 25 letters in response to the November 15, 2002, proposal and notice to reopen the comment period. Each of these letters contained one or more comments. Responses were received from industry, trade associations, consumers, consumer advocacy organizations, academia, health care professionals, professional societies, city and State governments, other Federal agencies, and other countries. Some of the comments supported the proposal generally or supported aspects of the proposal. Other comments objected to specific provisions and requested revisions. Some comments requested that the proposal be withdrawn or repropose. A few comments addressed issues outside the scope of the proposal and will not be discussed here. On September 18, 2001, the Office of Information and Regulatory Affairs

(OIRA), Office of Management and Budget, sent to the Secretary of the Health and Human Services (the Secretary) a letter requesting that the Secretary and FDA consider giving greater priority to the November 1999 proposal (Ref. 156) in light of the growing body of scientific evidence suggesting that consumption of *trans* fatty acids in foods increases the consumer's risk of developing CHD. The estimated public health benefits from increased consumer awareness of *trans* fat content in foods that were described in FDA's preliminary Regulatory Impact Analysis in the November 1999 proposal, and the subsequent evidence found in more recent studies, strongly support the interests of the Government to lower the incidence of and economic burden of CHD in the United States. This final rule summarizes the relevant comments that were received in response to the November 1999 proposal and provides the agency's conclusions regarding the labeling of *trans* fat on the Nutrition Facts panel.

A summary of the relevant comments that pertain to nutrition labeling of *trans* fat, the agency's responses to the comments, and a discussion of the agency's conclusions follow.

II. Highlights of the Final Rule

In this final rule and given the current state of scientific knowledge, FDA is requiring the mandatory declaration in the nutrition label of the amount of *trans* fatty acids present in foods, including dietary supplements. The declaration of this nutrient must be on a separate line immediately under the declaration for saturated fat but it will not include a %DV that is required for some of the other mandatory nutrients, such as saturated fat. In addition, the agency is withdrawing those sections of the proposed rule pertaining to the definition of nutrient content claims for "free" and for "reduced" levels of *trans* fatty acids, and limits on the amounts of *trans* fatty acids, wherever saturated fatty acid limits are placed on nutrient content claims, health claims, and disclosure and disqualifying levels. Further, the agency is withdrawing the proposed requirement to include a footnote stating: "Intake of *trans* fat should be as low as possible."

The action the agency is taking in this final rule is based on its evaluation of comments received in response to the November 1999 proposal, the reopening of the comment period on November 15, 2002, and on scientific evidence that shows that consumption of *trans* fatty acids increases LDL-C, a primary risk factor for CHD. The scientific evidence includes current authoritative reports,

such as Dietary Guidelines 2000 (Ref. 87), that recommend that Americans cut back on *trans* fats when reducing fat intake. The agency concludes that the declaration of this nutrient on a separate line, will help consumers understand that *trans* fat is chemically distinct from saturated fat and will assist them in maintaining healthy dietary practices. The agency intends to promote consumer awareness and understanding of the health effects of *trans* fat as part of an educational program. FDA is issuing an ANPRM elsewhere in this issue of the **Federal Register** that will solicit comment and additional consumer research that potentially could be used to establish new nutrient content claims about *trans* fat, to establish qualifying criteria for *trans* fat in certain nutrient content claims and health claims, and to establish disclosure and disqualifying criteria for *trans* fat. In addition, the ANPRM is soliciting comment on whether it should consider statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts panel or as a disclosure statement in conjunction with claims to enhance consumer's understanding about cholesterol-raising lipids.

III. Legal Authority

General Comments

FDA received a number of comments from trade associations and others in industry asserting that FDA did not meet its burden under the first amendment in proposing to mandate nutrition labeling of *trans* fat. Further, the comments asserted that FDA did not meet its first amendment burden for establishing restrictions on specific claims by virtue of how FDA defined nutrient content claims or established disqualifying and disclosure levels, including the effects that those actions would have on restricting certain health claims on food. In addition, comments raised questions about whether the agency's proposed action was consistent with the Administrative Procedure Act (APA) and whether the agency was acting consistent with its authority under the act.

As stated in section VI of this document, FDA is withdrawing those sections of the rule pertaining to the definition for nutrient content claims that were proposed, and to limits on the amounts of *trans* fatty acids wherever saturated fatty acid limits are placed on nutrient content claims, health claims, and disclosure and disqualifying levels. Further, the agency is withdrawing the proposed requirement to include a

footnote stating "Intake of *trans* fat should be as low as possible." The agency provides an overview of comments received on these withdrawn sections in section VI of this document, and therefore, is not addressing those comments here. Thus, the agency is addressing only those comments that pertain to legal issues about the agency's action to require mandatory *trans* fat labeling.

A. Statutory Authority

Several comments question whether the agency's proposed requirement for mandatory *trans* fat labeling would prevent consumer deception or would assist consumers in maintaining healthy dietary practices. The comments suggest that the data do not support mandatory *trans* fat labeling, unless the label contains a nutrient content or health claim related to fat or cholesterol or unless polyunsaturated fat or monounsaturated fat is voluntarily declared on the label. Specifically, the comments assert that mandatory *trans* fat labeling in the absence of claims, or statements about other fats, would not assist consumers in following healthy dietary practices or would not prevent consumer deception.

A few comments suggest that there was no basis for concluding any health benefit can be expected from disclosure of *trans* fat levels on foods when present in amounts that have not been clinically shown to have a material impact on human health or disclosure on foods with a trivial contribution of fat.

Another comment argues that the agency could only require mandatory labeling of *trans* fat under the statute where the absence of such labeling constitutes the omission of a material fact under section 201(n) of the act (21 U.S.C. 321(n)), such as when nutrient content claims are made about cholesterol or fatty acids, or when polyunsaturated and monounsaturated fats are voluntarily listed. A related comment suggests that *trans* fat labeling would be appropriate where the declaration of "total fat" and "saturated fat," that did not explicitly include *trans* fat, were established as misleading under section 201(n) of the act (without *trans* fat listed). The comment seems to suggest that the declaration of "total fat" and "saturated fat" in that situation would be misleading if the actual nutrition contribution from *trans* fat that such products make to the diet was greater in comparison to other products. In addition, one comment suggests that mandatory nutrition labeling of *trans* fat can only be "material" where there is sufficient *trans* fat present in the food to significantly impact the overall fatty

acid contribution that the food makes to the diet, such that only having total fat and saturated fat on the label would misrepresent the nutritional value of the product in a material way.

FDA believes it has adequate authority to adopt this rule. FDA's authority under the act to require *trans* fat labeling includes sections 201(n), 403(a)(1) and (q), and 701(a) of the act (21 U.S.C. 371(a)). FDA has authority under section 701(a) of the act to issue regulations for the efficient enforcement of the act. FDA can require labeling of certain facts that are material in light of representations made in the labeling or with respect to consequences which may result from the use of the article in order for a product not to be misbranded under sections 201(n) and 403(a) of the act. Further, under section 403(q)(2)(A) of the act, the Secretary (and FDA, by delegation) may require that information relating to a nutrient be in the labeling of food for the purpose of "providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices."

The agency believes that the data in the record supports mandatory *trans* fat labeling to ensure that consumers are not misled and are adequately informed about the product's attributes. Accordingly, FDA believes that mandatory *trans* fat labeling is necessary for foods not to be misbranded under section 403(a) of the act. The absence of information about the content of *trans* fat in foods that are subject to mandatory labeling would constitute an omission of a material fact under section 201(n) of the act.

Under the act, the agency has the mandate to ensure that labeling provides truthful and nonmisleading information to consumers. Thus, the law provides the agency with authority to require specific label statements when needed for reasons other than to ensure the safe use of food. Under section 403(a)(1) of the act, a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the act amplifies what is meant by "misleading" in section 403(a)(1) of the act. Section 201(n) of the act states that, in determining whether labeling is misleading, the agency shall take into account not only representations made about the product, but also the extent to which the labeling fails to reveal facts material in light of such representations made or suggested in the labeling or material with respect to consequences which may result from use of the article to which the labeling relates under the conditions of use prescribed in the labeling or under such

Department of Legislative Services
Maryland General Assembly
2007 Session

FISCAL AND POLICY NOTE

House Bill 91 (Delegate Hubbard)
Health and Government Operations

Food Service Facilities - Artificial Trans Fat - Prohibition

This bill prohibits food containing artificial trans fat from being stored, distributed, held for service, used in preparation of any menu item, or served in any food service facility. The prohibition does *not* apply to food served directly to patrons in the original sealed manufacturer's package. A violation will *not* affect a food service facility's license. A violator is *not* subject to: a fine or imprisonment; any notification by the Department of Health and Mental Hygiene (DHMH) of corrective actions required; or a DHMH order to abate the violation.

The bill takes effect October 1, 2008.

Fiscal Summary

State Effect: The bill's requirement to maintain an online list of noncompliant food service facilities could be handled with existing DHMH budgeted resources. Expenditures at State facilities serving food are not expected to increase as a result of this bill because of an assumed increase in availability of food products that do not contain artificial trans fat. No effect on revenues.

Local Effect: Existing local health department staff could monitor compliance within existing resources.

Small Business Effect: Meaningful for food service facilities that currently are using specified products with artificial trans fat and would not stop using those products without the bill.

Analysis

Bill Summary: A food contains artificial trans fat if the food is either labeled as containing, lists as an ingredient, or contains vegetable shortening, margarine, or any kind of partially hydrogenated vegetable oil. Any food with a nutrition facts label or other manufacturer documentation that lists less than 0.5 grams of trans fat per serving is *not* considered to contain artificial trans fat under the bill.

A food service facility must maintain on-site the original label for food that: contains fats, oils, or shortenings; is required by federal or State law to have a label when purchased; and is stored, distributed, held for service, used in preparation of any menu items, or served by the facility. A facility may provide manufacturer documentation acceptable to DHMH indicating whether the food contains artificial trans fat.

If a food is restricted under the bill and is not required to be labeled when purchased, a facility must obtain and maintain manufacturer documentation of whether the food contains artificial trans fat. The Secretary of Health and Mental Hygiene must adopt regulations that provide for a food service facility to obtain manufacturer documentation of food ingredients.

DHMH must list on its web site a food service facility that violates this bill. The facility must remain listed on the web site until DHMH finds the facility is in compliance with the bill.

Current Law: A food establishment must be licensed by DHMH and is subject to inspections. A food establishment is a food service facility or a food processing plant. If DHMH finds that a food establishment has violated the Maryland Food, Drug, and Cosmetic Act, or any regulation adopted under the Act, the licensee must be notified of the specific findings and the specific, reasonable date by which the licensee must correct the violations or deficiencies. If corrections are not made by the specified date, DHMH may suspend or revoke the food establishment's license.

Background: Trans fat increases a person's low-density lipoprotein (LDL), also known as "bad cholesterol," levels which increases a person's risk of coronary heart disease.

Trans fat is made when hydrogen is added to vegetable oil. Food manufacturers use trans fat because it increases a food's shelf life and stabilizes its flavors, according to the U.S. Food and Drug Administration (FDA). Trans fat can be found in vegetable shortenings, some margarines, crackers, cookies, snack foods, and other foods that are made with or fried in partially hydrogenated oils. The FDA requires food manufacturers

to list trans fat on all their products on the Nutrition Facts panel directly under the line for saturated fat.

The New York City Board of Health voted December 5, 2006 to require all restaurants in the city to remove artificial trans fat over an 18-month period. Effective July 1, 2007, with some exceptions, no foods containing artificial trans fat that are used for frying or in spreads may be stored, distributed, held for service, used in preparation of any menu item, or served in any food service establishment or by any mobile food unit commissary. This restriction applies to oils or shortenings used for deep frying of yeast dough or cake batter and all other foods containing artificial trans fat beginning July 1, 2008. A food with less than 0.5 grams per serving of trans fat is not considered to contain artificial trans fat. Establishments and commissaries must maintain food product labels or approved documentation for specified food products.

Any violation of the New York City health code carries a potential penalty of \$200 to \$2,000 depending on the egregiousness of the violation. A violation of the artificial trans fat ban would not count against a restaurant or bakery during the inspection process. The city's Department of Health and Mental Hygiene is providing restaurants and bakeries with technical assistance to help them comply with the ban's requirements.

State Expenditures: The Department of Legislative Services (DLS) assumes that given the increased public attention on limiting artificial trans fat and an increasing number of products that are available without artificial trans fat, food service establishments are already beginning to stock food items that comply with the artificial trans fat ban.

As a result, general fund expenditures for DHMH would not be affected by the ban because existing local health department sanitarians could incorporate the artificial trans fat ban into their existing inspections of food service facilities. DLS further assumes that existing DHMH staff could maintain an online list of any noncompliant food service facilities. Additionally, DLS assumes an increase in food expenditures for the State, such as State residential facilities, prisons, and schools, would be minimal and would likely occur regardless of this bill as more food items are made without artificial trans fat due to increasing public concern about this food additive.

DHMH's Community Health Administration (CHA) estimates that general fund expenditures could increase by \$1,412,968 in fiscal 2009 for grants to local health departments to collectively hire 33 sanitarians to inspect food service establishments because the time it would take to inspect these establishments would increase. The estimate also assumes DHMH hiring a sanitarian at CHA to maintain the restaurant database and provide technical support and training to the local health department

sanitarians. CHA estimates that of the approximately 30,000 retail and food service outlets, approximately 15,000 of those would be affected by the artificial trans fat ban.

CHA advises that it currently takes a sanitarian from two to three hours to conduct a food service facility inspection and that most facilities are inspected at least two times per year. If sanitarians were required to review product food labels as well, DHMH estimates that the time it takes a sanitarian to complete his inspection would increase to four to five hours.

DHMH's Developmental Disabilities Administration estimates that the artificial trans fat prohibition could increase the cost for ingredients and food preparation from 40% to 75% at its State residential facilities for individuals with developmental disabilities.

However, DHMH's Mental Hygiene Administration advises that it does not expect the bill to affect food expenditures at its State residential facilities because it anticipates that by the bill's October 1, 2008 effective date, many products without trans fats will be available.

The Department of Public Safety and Correctional Services' Division of Correction states that the bill is not expected to increase its expenditures.

Local Fiscal Effect: DLS assumes that given the increased public attention on limiting artificial trans fat and an increasing number of products that are available without artificial trans fat, food service establishments are already beginning to stock food items that comply with the artificial trans fat ban.

Existing local health department sanitarians could incorporate the artificial trans fat ban into their existing inspections of food service facilities.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Judiciary (Administrative Office of the Courts); Department of Health and Mental Hygiene; Office of the Attorney General (Consumer Protection Division); Department of Public Safety and Correctional Services; New York City Department of Health and Mental Hygiene Board of Health; *Revealing Trans Fats*, U.S. Food and Drug Administration; Department of Legislative Services

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Analysis by: Lisa A. Daigle

Direct Inquiries to:
(410) 946-5510
(301) 970-5510

Department of Legislative Services
Maryland General Assembly
2007 Session

FISCAL AND POLICY NOTE

Senate Bill 504
Finance

(Senator Forehand, *et al.*)

Food Service Facilities - Use of Artificial Trans Fat - Prohibition

This bill prohibits food containing artificial trans fat from being stored, distributed, held for service, used in preparation of any menu item, or served in any food service facility. The prohibition does *not* apply to food served directly to patrons in the original sealed manufacturer's package. A violator is *not* subject to a fine or imprisonment. A violator would be subject to notification by the Department of Health and Mental Hygiene (DHMH) of corrective actions required or a DHMH order to abate the violation, including the potential suspension or revocation of a license.

The bill takes effect October 1, 2008.

Fiscal Summary

State Effect: Potential significant increase in DHMH general fund expenditures beginning in FY 2009 if grants to local health departments increase to cover additional staffing costs for inspections of food service facilities facing corrective actions. General fund expenditures for DHMH could increase by \$100,000 in FY 2009 only to print trans fat pamphlets. Expenditures at State facilities serving food are not expected to increase as a result of this bill because of an assumed increase in availability of food products that do not contain artificial trans fat. No effect on revenues.

(in dollars)	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013
Revenues	\$0	\$0	\$0	\$0	\$0
GF Expenditure	100,000	-	-	-	-
Net Effect	(\$100,000)	\$0	\$0	\$0	\$0

Note: () = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate effect

Local Effect: Potential increase in local health department expenditures for increased staffing costs if additional inspections of noncomplying food service facilities are required because a facility may face corrective actions for failure to comply with the bill. It is assumed that local health departments could distribute trans fat pamphlets to consumers and add a link on their web site to DHMH's list of noncompliant businesses with existing resources. Potential loss of revenues for any food service establishment license revoked as a result of the bill. A food service establishment license fee is \$300.

Small Business Effect: Meaningful for food service facilities that currently are using specified products with artificial trans fat and would not stop using those products without the bill.

Analysis

Bill Summary: A food contains artificial trans fat if the food is labeled as containing, lists as an ingredient, or contains vegetable shortening, margarine, or any kind of partially hydrogenated vegetable oil. Any food with a nutrition facts label or other manufacturer documentation that lists less than 0.5 grams of trans fat per serving is *not* considered to contain artificial trans fat under the bill.

A food service facility must maintain on-site the original label for food that: contains fats, oils, or shortenings; is required by applicable federal or State law to have a label when purchased; and is stored, distributed, held for service, used in preparation of any menu items, or served by the facility. Instead of providing the original label, a facility may provide manufacturer documentation indicating whether the food contains artificial trans fat. If a food is restricted under the bill and is not required to be labeled when purchased, a facility must obtain and maintain manufacturer documentation of whether a food contains artificial trans fat. The Secretary of Health and Mental Hygiene must adopt regulations that provide the required documentation.

DHMH must maintain on its web site a list of food service facilities for each county that are in violation of the bill. DHMH must consult with the local health departments to provide an Internet link on each of the local health departments' web sites to the information on noncomplying facilities. DHMH also must coordinate with the local health departments to provide education and outreach on trans fat for consumers

Current Law: A food establishment must be licensed by DHMH and is subject to inspections. A food establishment is a food service facility or a food processing plant. A food establishment license fee is \$300 and is renewed annually. If DHMH finds that a food establishment has violated the Maryland Food, Drug, and Cosmetic Act, or any

regulation adopted under the Act, the licensee must be notified of the specific findings and the specific, reasonable date by which the licensee must correct the violations or deficiencies. If corrections are not made by the specified date, DHMH may suspend or revoke the food establishment's license.

Background: Trans fat increases a person's low-density lipoprotein (LDL), also known as "bad cholesterol," levels which increases a person's risk of coronary heart disease.

Trans fat is made when hydrogen is added to vegetable oil. Food manufacturers use trans fat because it increases a food's shelf life and stabilizes its flavors, according to the U.S. Food and Drug Administration (FDA). Trans fat can be found in vegetable shortenings, some margarines, crackers, cookies, snack foods, and other foods that are made with or fried in partially hydrogenated oils. The FDA requires food manufacturers to list trans fat on all their products on the nutrition facts panel directly under the line for saturated fat.

The New York City Board of Health voted December 5, 2006 to require all restaurants in the city to remove artificial trans fat over an 18-month period. Effective July 1, 2007, with some exceptions, no foods containing artificial trans fat that are used for frying or in spreads may be stored, distributed, held for service, used in preparation of any menu item, or served in any food service establishment or by any mobile food unit commissary. This restriction applies to oils or shortenings used for deep frying of yeast dough or cake batter and all other foods containing artificial trans fat beginning July 1, 2008. A food with less than 0.5 grams per serving of trans fat is not considered to contain artificial trans fat. Establishments and commissaries must maintain food product labels or approved documentation for specified food products.

Any violation of the New York City health code carries a potential penalty of \$200 to \$2,000 depending on the egregiousness of the violation. A violation of the artificial trans fat ban would not count against a restaurant or bakery during the inspection process. The city's Department of Health and Mental Hygiene is providing restaurants and bakeries with technical assistance to help them comply with the ban's requirements.

State Expenditures: The Department of Legislative Services (DLS) assumes that given the increased public attention on limiting artificial trans fat and an increasing number of products that are available without it, food service establishments are already beginning to stock food items that comply with the artificial trans fat ban.

However, because a food service facility may face corrective actions, including the suspension or revocation of a license, local health department sanitarians may need to make additional inspections of any noncomplying facilities. As a result, general fund

expenditures could increase for DHMH to increase local health department grants to cover any additional staffing costs. DLS further assumes that existing DHMH staff could maintain an online list of any noncompliant food service facilities. Additionally, DLS assumes an increase in food expenditures for the State, such as State residential facilities, prisons, and schools, would be minimal and would likely occur regardless of this bill as more food items are made without artificial trans fat due to increasing public concern about this food additive.

Local Fiscal Effect: Since a food service facility may face corrective actions, including the suspension or revocation of a license, for not complying with the trans fat ban, local health department sanitarians may need to make additional inspections of any noncomplying facilities. As a result, local health department expenditures could increase to cover any related staffing costs.

There could be a potential loss of local health department revenues if a food service establishment license is revoked from a facility that does not comply with the bill. The license fee is \$300 paid annually.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Judiciary (Administrative Office of the Courts), Office of Administrative Hearings, Department of Health and Mental Hygiene, Office of the Attorney General (Consumer Protection Division); Department of Public Safety and Correctional Services; New York City Department of Health and Mental Hygiene Board of Health; *Revealing Trans Fats*, U.S. Food and Drug Administration; Department of Legislative Services

Fiscal Note History: First Reader - March 7, 2007
ncs/jr

Analysis by: Lisa A. Daigle

Direct Inquiries to:
(410) 946-5510
(301) 970-5510

Department of Legislative Services
Maryland General Assembly
2007 Session

FISCAL AND POLICY NOTE

Senate Bill 633

(Senator Raskin, *et al.*)

Finance and Education, Health, and Environmental Affairs

Food Containing Artificial Trans Fat - Prohibition

This bill prohibits food containing artificial trans fat from being stored, distributed, held for service, used in preparation of any menu item, or served in a public school, a public institution of higher education, or a State-owned or operated food establishment. A violator is *not* subject to a fine or imprisonment. A food contains artificial trans fat if the food is either labeled as containing, lists as an ingredient, or contains vegetable shortening, margarine, or any kind of partially hydrogenated vegetable oil. Any food with a nutrition facts label or other manufacturer documentation that lists less than 0.5 grams of trans fat per serving is *not* considered to contain artificial trans fat under the bill.

Fiscal Summary

State Effect: Expenditures at State facilities serving food are not expected to increase as a result of this bill because of an assumed increase in availability of food products that do not contain artificial trans fat. Potential minimal loss of revenues if patrons choose to go to other nearby restaurants as a result of the bill, which is expected to be infrequent. Potential decrease in higher education revenues to the extent that the bill affects contracts with national restaurants chains leasing space on college campuses.

Local Effect: Food expenditures at local public schools and community colleges are not expected to increase as a result of the bill because of an assumed increase in the availability of food products that do not contain artificial trans fat. Any expenditure increase that is incurred would be passed on to students in the form of higher meal prices. Potential minimal loss of revenues at schools and colleges to the extent that individuals choose to go to nearby restaurants instead of eating at schools or colleges as a result of the bill. This is not expected to frequently occur. Existing local health department staff could monitor compliance within existing resources.

Small Business Effect: Potential minimal increase in revenues for small business food service facilities if individuals choose not to eat at food service facilities subject to the trans fat ban and instead choose to go to nearby facilities. Any increase as a result of the bill is assumed to be minimal.

Analysis

Current Law: A food establishment must be licensed by the Department of Health and Mental Hygiene (DHMH) and is subject to inspections. A food establishment is a food service facility or a food processing plant. If DHMH finds that a food establishment has violated the Maryland Food, Drug, and Cosmetic Act, or any regulation adopted under the Act, the licensee must be notified of the specific findings and the specific, reasonable date by which the licensee must correct the violations or deficiencies. If corrections are not made by the specified date, DHMH may suspend or revoke the food establishment's license.

Background: Trans fat increases a person's low-density lipoprotein, also known as "bad cholesterol," levels which increases a person's risk of coronary heart disease.

Trans fat is made when hydrogen is added to vegetable oil. Food manufacturers use trans fat because it increases a food's shelf life and stabilizes its flavors, according to the U.S. Food and Drug Administration (FDA). Trans fat can be found in vegetable shortenings, some margarines, crackers, cookies, snack foods, and other foods that are made with or fried in partially hydrogenated oils. The FDA requires food manufacturers to list trans fat on all their products on the Nutrition Facts panel directly under the line for saturated fat.

The New York City Board of Health voted December 5, 2006 to require all restaurants in the city to remove artificial trans fat over an 18-month period. Effective July 1, 2007, with some exceptions, no foods containing artificial trans fat that are used for frying or in spreads may be stored, distributed, held for service, used in preparation of any menu item, or served in any food service establishment or by any mobile food unit commissary. This restriction applies to oils or shortenings used for deep frying of yeast dough or cake batter and all other foods containing artificial trans fat beginning July 1, 2008. A food with less than 0.5 grams per serving of trans fat is not considered to contain artificial trans fat. Establishments and commissaries must maintain food product labels or approved documentation for specified food products.

Any violation of the New York City health code carries a potential penalty of \$200 to \$2,000 depending on the egregiousness of the violation. A violation of the artificial trans fat ban would not count against a restaurant or bakery during the inspection process. The city's Department of Health and Mental Hygiene is providing restaurants and bakeries with technical assistance to help them comply with the ban's requirements.

State Expenditures: The Department of Legislative Services (DLS) assumes that given the increased public attention on limiting artificial trans fat and an increasing number of products that are available without artificial trans fat, food service establishments in public institutions of higher education and State-owned and -operated food establishments are already beginning to stock food items that comply with the artificial trans fat ban.

However, because private food service establishments would not be required to ban artificial trans fat, there may be individuals who decide to no longer purchase food at the specified establishments with the trans fat ban and instead go to a nearby food service establishment that does. The frequency with which that would occur and the resulting fiscal impact cannot be reliably estimated at this time but is expected to be minimal.

General fund expenditures for DHMH would not be affected by the ban because existing local health department sanitarians could incorporate the artificial trans fat ban into their existing inspections of food service facilities in these affected establishments. Additionally, DLS assumes an increase in food expenditures for the State, such as State residential facilities, prisons, and schools, would be minimal and would likely occur regardless of this bill as more food items are made without artificial trans fat due to increasing public concern about this food additive.

The Maryland School for the Deaf advises that it stopped offering students foods that contain trans fat several years ago. St. Mary's College of Maryland's food service operation also does not use foods containing trans fats, although the college's bookstore/convenience store and vending machines do contain products with trans fats. Morgan State University advises that the bill would not have a fiscal impact on the university.

Although most University System of Maryland (USM) institutions do not expect the bill to have a significant impact on finances, the University of Maryland, College Park (UMCP) advises that the bill would impact revenues derived from national chain restaurants that lease space on campus. USM advises that the restaurants could be forced to eliminate products from their menus, decreasing student purchases at the restaurants and the revenue that UMCP derives from the purchases. If sales drop significantly, existing lease contracts could be restructured or withdrawn resulting in lost revenues for

USM. DLS assumes that any loss of patrons at UMCP facilities that results from the bill would be minimal because of increased attention among businesses to limit artificial trans fats. For example, Papa John's does not include trans fats in its pizzas or other menu items, according to the company's web site.

Local Expenditures: DLS assumes that given the increased public attention on limiting artificial trans fat and an increasing number of products that are available without artificial trans fat, food service establishments in public schools and community colleges are already beginning to stock food items that comply with the artificial trans fat ban. Therefore, any increases in expenditures that results from the bill is expected to be minimal and would be recovered through higher food prices. Public schools and community colleges could potentially experience a minimal loss of revenues to the extent that individuals choose to go to nearby restaurants instead of eating at a public school food service facility as a result of the bill. Existing local health department staff could monitor compliance within existing resources.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Montgomery County, Prince George's County, Caroline County, Maryland School for the Deaf, Maryland State Department of Education, St. Mary's College, Morgan State University, Department of Health and Mental Hygiene, University System of Maryland, Maryland Higher Education Commission, Baltimore City, New York City Department of Health and Mental Hygiene Board of Health; *Revealing Trans Fats*, U.S. Food and Drug Administration; Department of Legislative Services

Fiscal Note History: First Reader - March 7, 2007
ncs/jr

Analysis by: Lisa A. Daigle

Direct Inquiries to:
(410) 946-5510
(301) 970-5510



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Isiah Leggett
County ExecutiveUma S. Ahluwalia
Director

MEMORANDUM

028394

May 10, 2007

TO: Marilyn J. Praisner, President
Montgomery County Council

FROM: Uma S. Ahluwalia, Director *Uma*

SUBJECT: Amendment to the Trans Fat Regulation

2007 MAY 11 AM 8:25

RECEIVED
MONTGOMERY COUNTY
COUNCIL

Thank you for the opportunity to comment on the proposed amendment to the Trans Fat Regulation. It allows for phasing in of the requirement for eating and drinking establishments to eliminate trans fats. If the regulation incorporated this phase-in component, the Department's workload would primarily be related to verifying compliance at each stage of the storage, preparation, display, and service process. The phase in appears straight forward as stated in subsection (g): to eliminate oils, shortenings and margarines with artificial trans fats that are used for frying or in spreads by January 1, 2008; and to eliminate oils or shortenings used in deep frying of yeast dough or cake batter and all other foods containing trans fats by January 1, 2009. This reasonably aligns with our mission and staff skills.

The proposed amendment also permits any eating and drinking establishment the opportunity to apply for a time-limited waiver from the requirement to eliminate trans fats in products covered under subsection (h). This waiver could be up to one year if the establishment demonstrates that a suitable replacement product is not widely commercially available. This introduces a very significant complication to the management/administrative side of enforcing the law. Complying with this option requires judgment and knowledge of the national and international food industry's products, production, and sales patterns that the staff would need to develop. The Department believes that staff members will encounter many unclear situations as they attempt to implement the waiver. New York was prudent in not opening this subject area.

- Testimony at last week's worksession described products made entirely outside the eating and drinking establishment by an international corporation (the example used was Sara Lee pies). The restaurant merely opened and served the pie. Do we deny the request for an additional year for a baked good having trans fats if another major company sells a similar product which has no trans fats? What if a locally available product might be known to us? Should we insist the restaurant use another brand because it is available and trans fat free, even though the restaurant must trade off putting the company name on the menu?

Office of the Director

- If the amendment were adopted, the Department would need guidance on whether it is our obligation to protect the public from the long term effects of trans fats or to prevent disruption to the restaurant's business for an additional year. What do we do with the national chain franchise in our County which can't use readily available trans fat free products because the national chain's product has trans fats?
- An application for extension may be an easy avenue for many licensees to request. The Department could get a large number of licensees making multiple requests for waivers on multiple food products served in their facility.

The Department believes that it will be time consuming to provide information to the Council on a case-by-case basis for all eating and drinking establishments that seek a waiver from the regulation. If the Council wishes the Department to grant waivers, the Department suggests that it send the Council a summary report after the window of applying for the waiver and decision making closes.

In summary, the Department does not have the expertise, capacity, or core mission to engage the entire international food industry in this area to make the required determinations competently or equitably at this time. The Department appreciates the importance of the appearance of equity to the community as well as the internal confidence that our decisions are thorough and consistent. The resource requirements to achieve these outcomes are substantial.

Recommendation

The Department suggests that it return three months before phase two – the baked goods requirement – goes into effect with a report on whether the implementation date for baked goods should be postponed generally, not on a product by product, facility by facility basis. If the Council adopts this suggestion, the Department would need funds to hire a consultant with the necessary expertise to complete the report.

USA:gh